UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ERFINDERGEMEINSCHAFT UROPEP GBR	DOCKET 2:15CV1202
VS.	APRIL 21, 2017
ELI LILLY AND COMPANY AND BROOKSHIRE BROTHERS, INC.	8:02 A.M.
	MARSHALL, TEXAS

VOLUME 5 OF 5, PAGES 1386 THROUGH 1514

REPORTER'S TRANSCRIPT OF JURY TRIAL

BEFORE THE HONORABLE WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE

APPEARANCES:

FOR THE PLAINTIFF:

ADAM K. MORTARA
J. SCOTT MCBRIDE
BENJAMIN J. WHITING
ALEX L. GRODEN
BARTLIT, BECK, HERMAN, PALENCHAR & SCOTT
54 WEST HUBBARD STREET, SUITE 300
CHICAGO, ILLINOIS 60654

JOHN M. HUGHES
NOSSON D. KNOBLOCH
BARTLIT, BECK, HERMAN, PALENCHAR & SCOTT
1899 WYNKOOP STREET, SUITE 800
DENVER, COLORADO 80202

MELISSA R. SMITH
GILLAM & SMITH
303 SOUTH WASHINGTON AVENUE
MARSHALL, TEXAS 75670

COUNSEL FOR DEFENDANT ELI LILLY AND COMPANY:

TODD G. VARE
JEFF M. BARRON
BARNES & THORNBURG
11 SOUTH MERIDIAN STREET
INDIANAPOLIS, INDIANA 46204

VICTOR D. VITAL
JON B. HYLAND
BARNES & THORNBURG
2100 MCKINNEY AVENUE, SUITE 1250
DALLAS, TEXAS 75201

FELICIA J. BOYD
ANTHONY SON
BARNES & THORNBURG
225 SOUTH SIXTH STREET, SUITE 2800
MINNEAPOLIS, MINNESOTA 55402

COURT REPORTER: CHRISTINA L. BICKHAM, CRR, RMR
FEDERAL OFFICIAL REPORTER
300 WILLOW, SUITE 221
BEAUMONT, TEXAS 77701

PROCEEDINGS RECORDED USING COMPUTERIZED STENOTYPE;
TRANSCRIPT PRODUCED VIA COMPUTER-AIDED TRANSCRIPTION.

INDEX

(Open court, all parties present, jury not present.)

THE COURT: All right. The first order of business is to see if folks want to renew their Rule 50 motions. Do you have something before that?

MR. MORTARA: We just found a typo in the jury instructions, but it can wait for the jury instructions section.

THE COURT: This is the set of jury instructions that you have now or --

MR. MORTARA: It was from the one yesterday. There is a missing "not" in the written description instruction.

THE COURT: Oh, dear. Where is it?

MR. MORTARA: Well, it was on page 16 at the end of "written description."

THE COURT: Page 16 -- okay. The pages have changed somewhat and --

MR. MORTARA: It is right before "enablement"; so if you find "enablement," it is the paragraph that precedes the beginning of "enablement."

THE COURT: "To summarize"?

MR. MORTARA: Yes. In the second sentence, at least in our version, it says, "If you find Lilly has met its burden, then you must find that the claim is not

invalid" instead of "has not met this burden."

MS. BOYD: Or the other "not."

THE COURT: Yeah. Either of the "nots" could go, but one of them has to go -- one has -- certainly either one has to go or one has to be added.

MR. MORTARA: Yeah. The previous sentence is --

THE COURT: If you find it has met the burden, then you must find that it is -- "has not met its burden." Yeah, right. Has "not" met its burden.

MR. MORTARA: Sorry about that, your Honor. We just saw it.

THE COURT: Well, I didn't see it at all; so, you're ahead of me.

MR. MORTARA: And to answer your first question, we would renew our motions that we made at the close of --

THE COURT: Right. Okay.

MR. MORTARA: -- defendant's case. We don't need to go through them, do we?

THE COURT: No. I think I have them all.

And you would renew yours as well, Mr. Barron.

MR. BARRON: Yes. Eli Lilly renews its as well.

THE COURT: All right. Now, I am going to

deny all of them except for the Rule 50 on willfulness, which I am going to grant; so, willfulness is out of the case.

MR. BARRON: Thank you, your Honor.

THE COURT: And there will be no instruction on willfulness.

Now, let me go through --

MR. BARRON: We have some additional Rule 50 motions to present, your Honor, prior to the charge.

THE COURT: That you didn't raise before?

MR. VARE: These would be after the close of our invalidity case.

THE COURT: I thought you had raised --

MR. BARRON: We did, your Honor, but before the close of --

THE COURT: Well, okay. Why don't you give them to me anyway. I'll hear them.

MR. VARE: Your Honor, it is really just -- these would be Rule 50 motions directed to our invalidity defenses.

THE COURT: All right.

MR. VARE: Whether or not you want to hear those now or whether or not they would be raised --

THE COURT: Let's hear them now, but I -- give them to me in bite-size form.

MR. VARE: Sure.

THE COURT: I'm familiar with the issues.

MR. VARE: Right. The Rule 50 motion on anticipation is that the evidence shows that the Cheung reference is a printed publication available to persons, you know, having an interest in the subject matter --

THE COURT: Right.

MR. VARE: -- and that it discloses all of the elements of the claim.

THE COURT: Okay.

MR. VARE: The Rule 50 motion would be also on written description, that the evidence meets the clear and convincing evidentiary standard to show that the inventors did not possess the full scope of the claim.

Third, the enablement issue, that the evidence in the record proves by clear and convincing evidentiary standard that the claims are not enabled to their full scope.

And then -- oh. And then, fourth, that the evidence in the record proves by clear and convincing evidentiary standard that the claims are obvious in view of the evidence.

THE COURT: All right. Those will each be denied.

MR. VARE: Thank you, your Honor.

THE COURT: Now, probably what makes the most sense is for me to see if I can intercept Ms. Greenwald and get her to make these changes because what I want to do is distribute to you the revised instructions and -- here she is now.

Under the universal principle that nothing is ever finished, we have actually found another typo which we need to fix because it is of some significance. It's one of those that is easy to overlook, obviously, because we've done it several times.

This is page -- let me go off the record a minute.

(Off the record, 8:07 a.m. to 8:08 a.m.)

THE COURT: All right. What I'm going to do is I have -- in light of the objections and discussion yesterday and the briefs -- and thank you for the briefs. They were quite helpful. I have made several of the proposed changes. I've made some changes that -- and I have decided not to make changes in other ways. Let me summarize the changes that I have made and not made on the points of disagreement.

And maybe what makes sense is if you can just give counsel at this point copies of the charge --

LAW CLERK: Sure.

THE COURT: -- with the understanding that the

typo will be corrected in the copies that we'll give to you and the final copies, obviously, that go to the jury. But I will let you know what the changes are, and I will give you an opportunity to renew your objections.

Now, let me understand that all of the objections you made yesterday preserve objections fully as far as I'm concerned. So, you don't have to -- I would recommend that you renew your objections just for the record, but you are not at risk of waiving anything as far as I'm concerned because you have put on the record your objections and those stand.

So, let me go through the materials. The first point is on the whole question of BPH and enlarged prostate. On page 6 we have added a sentence -- let's see. I'll get the page. This is to the definition of "treatment of benign prostatic hyperplasia," and here is how that paragraph will now read.

"The term 'treatment of benign prostatic hyperplasia' means the treatment of a medical condition known as benign prostatic hyperplasia (BPH) or the symptoms of BPH."

And there is a new sentence. "BPH is a condition in which an enlarged prostate results in lower urinary tract symptoms."

All right?

The next one, page 10. There were objections to the anticipation language. We are going to stay with the language that was in the prior version.

Page 15, we are going to retain the references to "the full scope of the invention" in the written description section.

Page 16, we're going to make a modification in the language of the written description discussion as follows, if I can find the spot. Yes. The sentence that starts -- the second sentence on that page that starts "It is not necessary."

"It is not necessary to describe every compound used in the claimed method by name or structure in order to satisfy the written description requirement as applied to a group of compounds as long as the patent includes a sufficient number of representative compounds or a common structural feature such that a person of ordinary skill in the art would understand from reading the patent" -- and your copy may have the word "in" after the word "reading," but that will be -- we caught that and that has been eliminated -- "that the inventor invented the full scope of the claimed method."

Okay. The next one is on page 16, four lines from the bottom, the words "full scope of" have been added to that claim.

All right. Additional points, just things that we are not putting in. The argument that the written description requires the description of both prophylaxis and treatment is not going to be given. There was no focus in this case on prophylaxis. The focus was exclusively on treatment.

So, as far as I can see, the burden being what it is, the idea that there is written description failure with respect to prophylaxis not presented by the case. And in any event, "prophylaxis" defined in a way that is encompassed within the broader notion of "treatment"; so, I think there is -- no separate written description is required.

On negative claim limitations, I have carefully considered your briefs and the cases that we discussed yesterday; and I am persuaded particularly by language in *Inphi* and *Johnson* that this is a case in which it is not necessary to have an elaborate written description for the excluded compounds -- and I would call your attention particularly to page 1356 of *Inphi* which cites Johnson and -- for the proposition that -- and I quote -- "the applicant narrowed the claims to exclude content of, in that case, a lost interference count and the court observed that it is for the inventor to decide what bounds of protection he will seek."

So, that will be denied.

I am not going to give the natural phenomenon argument instruction. We've called it by shorthand the 101 instruction, but it is not, I understand, a 101 instruction. Nonetheless, that will not be given.

Yes. And I'm not going to give the one or more species because, in my view, that suggests to the jury that one would always be necessarily sufficient, which is not the law.

All right. Those are my rulings. Now, if you like, because you haven't had very much time to look at the full instructions, I will give you time to consider them. I am required to get your objections on the record before the jury retires; so, if you would like, we can take a few minutes to give you an opportunity to look at the full text of the instructions and see if there is anything further, or if -- I've tried not to slip anything in on you, but -- I've tried to describe everything that I have changed or not changed, but you may want to confirm that for yourselves.

So, I will allow you to take a look at the materials; and when you are ready, you can make your objections.

And, again, if all you need to do or want to do is to renew your objections from yesterday, that is

fully sufficient.

All right.

MR. BARRON: Excuse me, your Honor. I'm going to step out of the room to consult with our client.

THE COURT: That's fine.

MR. BARRON: Thank you.

(Recess, 8:16 a.m. to 8:24 a.m.)

THE COURT: All right. Plaintiff objections?

MR. MORTARA: Your Honor, we would just prefer "one or more representative compounds"; so, we object to "sufficient number."

Thank you.

THE COURT: Okay. Defendant?

MR. BARRON: Your Honor, we renew our prior objections.

THE COURT: All right.

MR. BARRON: In addition, we point out that the anticipation instruction has some language regarding infringing with regard to what it means for a prior compound or prior use or prior publication to anticipate. We would object to that.

THE COURT: All right.

MR. BARRON: We maintain our objections to the written description including the use of the example. And, again, we just feel like it should be emphasized

representative of the species. We appreciate that your Honor has made some changes that we suggested, but I just need to maintain that objection.

THE COURT: All right.

MR. BARRON: We object based on all of the grounds that were raised in the briefing last night, including the negative claim limitation --

THE COURT: We understand each other, but I think for the benefit of Ms. Bickham, you have to slow down a little.

MR. BARRON: I will speak more slowly. My apologies.

In addition, we renew all of our prior claim construction positions and summary judgment positions, but the reason why I happen to mention that at this point is that we did have an alternative claim construction on prophylaxis; and, so, that would play into our objection --

THE COURT: Okay.

MR. BARRON: -- to that.

In addition, there was some evidence from Dr. Roehrborn in the record that demonstrated, we thought quite clearly, that that claim limitation was neither described or enabled. And, so -- the prophylaxis limitation. So, there would be an additional basis.

And I can go through what was filed last night, but if your Honor is satisfied that those objections have been preserved --

THE COURT: I am.

MR. BARRON: Okay. Give me one moment to consult.

THE COURT: All right.

MR. BARRON: My apologies, your Honor. I just -- just to be clear on the record, I think I understood you that the matters raised last night are all subject -- and those objections -- are all subject to objection, and those objections have been maintained.

THE COURT: Yes.

MR. BARRON: Thank you.

THE COURT: Yes. Everything that has been raised since the formal charge conference, including the briefing and including this morning, is preserved as objections to the court's charge, as far as I'm concerned; and I think -- well, I can't speak for the Court of Appeals, at least right now, but I think that should -- you should feel comfortable with my acknowledgment.

MR. BARRON: Thank you, your Honor. I appreciate you can't speak today for the Court of Appeals.

THE COURT: Right. My acknowledgment is that I fully understand your objections, and you've preserved them.

MR. BARRON: Thank you, your Honor.

THE COURT: All right. So, we'll bring the jury in in five minutes, and then I will give the charge, and then we'll go directly into the closing argument.

Let me see. My charge will probably take 30 to 40 minutes. I'm just wondering if -- let's see. So, we'll have an hour and a half -- I'm kind of reluctant to chop up the sequence of arguments with a break. But if we go without a break, that's a long time.

Yes, Mr. Hughes? What are you suggesting.

MR. HUGHES: Maybe we could have a brief break after the charge and let us get set up.

THE COURT: Why don't we do that. That's probably the most sensible place to break. Then we don't have the jury having heard somebody and they have ten minutes to digest it. And; so, we will break after the court's charge. It'll be a pretty quick break.

Yes, Mr. Vital.

MR. VITAL: Thank you very kindly, your Honor. I would also ask for just five minutes after the opening argument of counsel so I can set up a flip chart.

THE COURT: Well, we'll probably take ten.

MR. VITAL: Yes, sir.

THE COURT: All right. Good.

MR. VITAL: Thank you, your Honor.

THE COURT: Okay. That sounds like a good idea.

MR. BARRON: Your Honor, since we have a brief three minutes --

THE COURT: Well, we've got about one, actually.

MS. BOYD: I think it may only take one.

There are two exhibits that are being lodged that contain the kind of sensitive highly confidential Lilly information that was not fully discussed at trial. I believe both parties agree they should be maintained under seal.

THE COURT: Yes.

MR. BARRON: And they are exhibits, for the record, Plaintiff's Exhibit 81 and Plaintiff's Exhibit 319.

THE COURT: They will remain under seal. I assume we are not going to actually discuss the numbers in the course of --

MR. BARRON: I believe no further than they have already been discussed.

THE COURT: Right. Well, actually, but when

they were discussed, they were discussed in sections of the transcript that were then sealed so -- we did seal some of the transcript, you will recall, when the financial information was put on and Mr. Hughes discussed that information.

So, are we going to have a discussion of the particular numbers.

MR. BARRON: Certainly not from Lilly.

THE COURT: Well --

MR. BARRON: I don't believe so.

MR. HUGHES: No, your Honor.

THE COURT: Okay. Fine. We won't seal the transcript, then, unless something arises.

I think we are ready for the jury, Mr. Johnson.

(The jury enters the courtroom, 8:33 a.m.)

(Open court, all parties present, jury present.)

THE COURT: Ladies and gentlemen of the jury, you have now heard all of the evidence in this case. The time has come for me to instruct you on the law that you are to apply.

The legal term for what I am going to give you is the "jury charge," or the "court's instructions." These instructions will be a little bit lengthy, and they

may be a little difficult to follow at times. That's because the law in this case is fairly complex.

To help you, I have made copies of the instructions that will be available for you to use in the jury room. I mention this so you won't feel that you have to take notes right now or try to memorize what I'm saying. In fact, I would suggest that you just listen to the instructions without trying to write anything down. You will have copies in the jury room of exactly what I'm now saying.

Now, after I instruct you on the law, the attorneys will have an opportunity to make their closing arguments to you. When they do, you should keep in mind that statements and arguments of the attorneys are not evidence and are not instructions on the law. They are intended only to assist you in understanding the evidence and the parties' contentions.

When you return to the jury room, your job will be to consider the evidence you have heard and to decide what the facts are. As jurors, you are what we call the "finders of the facts." My job as the judge -- or as we sometimes refer to the judge as "the court" -- you will hear that term used from time to time; it's just me -- is to explain to you the law that you will apply to the facts.

You should not be concerned with the wisdom of any aspect of the applicable law that I state to you. Also, please remember that nothing I may have said or done during the course of the trial and nothing I say now is intended to suggest, or should be taken by you as suggesting, what I think your verdict should be.

As I go through these instructions, if anyone has a hard time hearing me or if I start to go too fast, just raise your hand; and I will slow down or I'll speak more loudly. Sometimes I have a tendency to speak too softly. And if I do, please just so indicate. Index.

Now, first with respect to the burden of proof, evidence, and the credibility of witnesses. I'm going to start by returning to the subject of the burden of proof that we briefly discussed at the beginning of the case.

For some of the issues in this case, such as whether Lilly infringes the '124 patent, the burden of proof is the preponderance of the evidence.

The "preponderance of the evidence" means that a party who is asserting a particular claim, such as UroPep saying that Lilly infringes its patent, has the burden of persuading you that the evidence supporting that claim is more likely to be true than untrue.

If the evidence does not persuade you that a

party's claim is more likely to be true than untrue, that means the party with the burden of proof has failed to satisfy that burden. If that happens, you should find in favor of the other party on that particular claim.

As I said before trial, some issues, such as whether UroPep's patent is invalid, have a different burden of proof. For these issues, the burden of proof is clear and convincing evidence.

Now, "clear and convincing evidence" means that a party who is asserting a particular claim, such as Lilly saying that UroPep's patent is invalid, has the burden of leaving you with a clear conviction or belief that the evidence supports that party's claim or defense. That is a higher standard of proof than the preponderance of the evidence, which means it is harder to prove something by clear and convincing evidence than by a preponderance of the evidence.

As the finders of the facts, you are responsible for weighing the evidence in this case, including the testimony of the witnesses you have heard, the exhibits that have been introduced as evidence, and any facts that the parties have agreed are true, such as by stipulation.

As a reminder, the lawyers' statements and characterizations of the evidence are not evidence.

While the opening and closing arguments may be helpful to you, your decision should ultimately depend on your evaluation of the evidence.

Now, as part of your job as jurors, you are entitled to weigh the testimony of the witnesses. This is a job that is well suited for jurors like yourselves who have heard and seen the witnesses.

For example, if two witnesses offer testimony that is in conflict, you should use your common sense in deciding which witness you think is more believable. You can consider, for example, each witness' motive, state of mind, knowledge, and manner while on the jury stand -- witness stand.

If there is a question as to the relative expertise of two witnesses, again, you should use your common sense to decide which witness you find more knowledgeable and more believable. You are entitled to give the testimony of each witness whatever weight you feel is appropriate. You may choose to believe or disbelieve any witness' testimony, either entirely or in part.

Now, you've heard some testimony about payments to witnesses. Parties in a lawsuit are allowed to provide reasonable payment to witnesses for travel expenses and the witness' loss of time.

Also, expert witnesses are typically compensated for their work by the party that hired them. Compensating such witnesses is permissible and is commonly done. The fact that a witness is paid does not mean that his testimony should not be believed.

On the other hand, the fact that a witness has testified as an expert does not mean that you must accept that witness' opinions as true. And in the case of any witness who is compensated in connection with this case, you may consider that fact to the extent that you conclude that it bears on possible bias on the part of the witness. In the end, as with all other witnesses, it is up to you to decide whether you find the witness' testimony to be convincing.

Now, during the trial, some of the testimony was presented not through a live witness but through a deposition. As you saw, a deposition is a recording of the witness' sworn answers to questions that were asked by the lawyers before the trial.

The deposition testimony that you heard at trial is entitled to the same consideration as any other evidence in the case, and you should judge its credibility and weight the same as if the witness had been present and testified from the witness stand.

Let me turn to the legal principles that apply

to this case. I'm going to start with UroPep's claim that Lilly has infringed its patent, which we have been referring to as the "'124 patent."

What is patent infringement? A patent, as you've heard since the original video that you saw, is issued by the U.S. Patent and Trademark Office. If the patent is valid, the owner of a patent has the right to stop others throughout the United States from using the invention that is claimed in the patent.

The right to exclude others lasts for 20 years from the date that the application for the patent was first filed. Here, the application for the '124 patent was first filed on July 9th, 1997; so, the patent will expire in a couple of months, on July 9th, 2017.

Patent infringement occurs when a person uses a product or method that is covered by the patent and does so without the patent owner's permission.

How do we decide what is covered by a patent? For that, we look at the patent's claims. The claims, as you know by now, are the numbered paragraphs at the end of the patent. These claims are important because it is the words of the claims that define what a patent covers.

As you've heard, UroPep asserts that Lilly has violated UroPep's rights in the '124 patent by inducing others to infringe claim 1 of the '124 patent. I will

say more a little later about the requirements for inducement of infringement, but first I'll give you a brief overview of the '124 patent.

The '124 patent, like any other patent, includes these numbered claims at the end of the patent. A patent claim can describe a product, such as a machine; or it can describe a method for doing something.

The claim at issue here, claim 1 of the '124 patent -- that's the only claim that's at issue -- is referred to as a "method claim" because it describes a method for treating BPH. Because only the claims of a patent can be infringed, you must understand the meaning of the claim before you do any infringement analysis.

There are several terms in the claim that I will define for you. I will give you my definitions of those terms after I read the claim to you. You are required to accept my definition of those words in the claim as correct.

You have a copy of claim 1 of the '124 patent in your notebooks. The claim is at the end of the patent, along with two other numbered claims if you want to follow along as I read it. Claim 1 is the only claim we are concerned with here.

So, claim 1 reads as follows: "A method for prophylaxis or treatment of benign prostatic hyperplasia

comprising administering to a person in need thereof an effective amount of an inhibitor of phosphodiesterase (PDE) V excluding a compound selected from the group consisting of" and then the claim lists eight chemical compounds by their chemical names that are specifically excluded from the coverage the claim, along with certain related compounds referred to as "pharmacologically compatible salts thereof."

Now, you will notice that claim 1 uses the word "comprising," which is a word that is used frequently in patent law but not very often in ordinary conversation. What it means is "including" or "containing."

So, a claim that uses the word "comprising" is not limited to methods or products having only the elements that are contained in the claims. It also covers methods or products that include additional elements.

For example, take a claim that covers a table. If the claim refers to a table "comprising" a tabletop, legs, and glue, the claim will cover any table that contains those structures, even if the table also contains other structures, such as a leaf or wheels on the legs.

I will now give you my definitions of other

terms that are used in claim 1 of the '124 patent.

The term "prophylaxis" means "prevention of the progression or development of the disease."

The term "treatment of benign prostatic hyperplasia" means "the treatment of the medical condition known as benign prostatic hyperplasia (BPH) or the symptoms of BPH." BPH is a condition in which an enlarged prostate results in lower urinary tract symptoms.

The term "administering" means "providing treatment, such as by implementing a course of action to address a health issue." "Administering" treatment can take the form of personally causing that course of action to be carried out or directing or supervising the treatment; that is, by issuing instructions to another person to carry out the course of action to address the health issue.

In the case of the administration of drugs, "administration includes direction or control over the use of the drug or the decision to use the drug."

The term "an effective amount" means "an amount that is effective to treat or prevent BPH."

And finally the term "an inhibitor of phosphodiesterase (PDE) V" means "a selective inhibitor of PDE5, which is at least 20 times more effective in

inhibiting PDE5 as compared to PDE1 through PDE4."

Again, I want to emphasize that you should not take my definitions of the language of the claim as any indication that I have a view regarding how you should decide the case or any of the issues that you are being asked to address, such as infringement and invalidity. Those issues are for you and for you alone to determine.

Now let me turn to induced infringement. UroPep alleges that Lilly indirectly infringes the '124 patent by inducing others to infringe. Now, induced infringement is a common form of patent infringement; but it takes a little explaining to make clear what it involves.

To prove induced infringement, UroPep has to prove three things: First, that someone carried out acts that directly infringed claim 1 of the '124 patent; second, that Lilly took actions that were intended to cause those acts of direct infringement; and, third, that Lilly was aware of the '124 patent and knew that those acts, if carried out, would infringe the patent.

So, if a person is charged with induced infringement of a patent, it is necessary to show that someone else directly infringed the patent. To determine whether a person infringes a method claim, you need to find that the person is using the method in a way that

includes each of the claim's elements.

If a person uses the method that is covered by a patent claim and if he does so without the patent owner's permission, then that person is said to directly infringe the patent.

Proving direct infringement does not require proving that the direct infringer intended to infringe the patent. Someone can be directly infringing the patent even if he does not know that the patent exists.

In addition, in order to prove induced infringement, it is necessary to show that the inducer intentionally encouraged, caused, or induced the direct infringer to infringe the patent. In order to find a party guilty of induced infringement, you must find that they were aware of the patent and knew that their acts caused others to infringe the patent.

Here's how these general concepts apply to this case: UroPep says that doctors and patients who prescribe or take Cialis directly infringe claim 1 of the '124 patent if they administer Cialis in an amount effective to treat BPH.

UroPep then charges Lilly with induced infringement by saying that Lilly actively induces those doctors and patients to prescribe or use Cialis in an amount effective to treat BPH.

In order to prove its case of induced infringement by Lilly, UroPep must prove several things by a preponderance of the evidence.

First, UroPep must prove direct infringement by doctors and patients. To do that, UroPep will have to prove that it is more likely than not that Cialis was being taken to treat the symptoms of BPH and that it is more likely than not that those symptoms were caused by BPH in those patients who were taking Cialis.

Second, UroPep must prove that it is more likely than not that Lilly took action intending to cause those infringing acts by doctors and patients.

And, third, UroPep must prove that it is more likely than not that Lilly was aware of the '124 patent and knew that the acts by the doctors and patients would infringe the patent.

If you find that Lilly was aware of the patent but believed that the acts it encouraged did not infringe the patent, Lilly is not liable for induced infringement.

On the other hand, if Lilly intended to cause direct infringement of the '124 patent and was aware of the existence of the patent, it does not matter whether Lilly may have believed that the '124 patent was invalid.

To summarize on infringement, if you find that UroPep has proved, by a preponderance of the evidence,

that Lilly has induced infringement of claim 1 of the '124 patent, you must find in favor of UroPep on the issue of infringement. If you do not so find, you must decide in favor of Lilly on that issue.

I'll next turn to patent invalidity. Even after a patent issues, the patent can be found invalid if a person challenging the patent can prove invalidity by clear and convincing evidence.

Lilly contends that claim 1 of the '124 patent is invalid and that Lilly is entitled to be found not liable for that reason. The claim terms are interpreted in the same way for invalidity as for infringement.

In patent law what came before the invention is often referred to as the "prior art." You've heard that term in the course of the trial. Patent lawyers often refer to each item of prior art as a "prior art reference."

For example, you might say that the telephone is prior art for the cell phone and that the cell phone is prior art for the smartphone. All that means is that things referred to as "prior art" or "prior art references" are those things that you are allowed to look at to see if a particular invention really is new and not obvious.

First, anticipation. If an invention that is

set forth in a patent claim is not new because the same invention was previously invented or described by someone else, we say that it was "anticipated" by the prior art and is not entitled to patent protection.

Lilly says that the '124 patent is anticipated by prior art. If you think Lilly has proved by clear and convincing evidence that claim 1 of the '124 patent is anticipated by the prior art, then that claim is invalid.

For the claim in this case to be invalid because it is anticipated by the prior art, Lilly must prove by clear and convincing evidence that all of the elements of the claim were present in a single prior art method or were described in a single previous printed publication.

A claim is anticipated if the prior art disclosed one or more compounds that was used in an infringing manner. To anticipate the invention, the prior art does not have to use the same words as the claim; but all of the elements of the claim must have been disclosed, either by being expressly stated or being implied in a way that a person familiar with the field of technology of the invention, upon looking at that one reference, could make and use the invention.

Now, in determining whether a single item of prior art anticipates a claim, you should consider not

only what is expressly disclosed in the particular prior art reference but also what is inherently present in that prior art or inherently results from its practice.

Prior art inherently anticipates a patent claim if the missing element or feature would necessarily result from what the single item of prior art teaches to persons of ordinary skill in the art.

A person claiming inherent anticipation must prove by clear and convincing evidence that the allegedly inherent element is necessarily present. Evidence outside of the prior art reference itself may not be used to show that the elements that are not expressly disclosed in the reference are inherent in it.

In order to be inherent, the feature that is alleged to have been inherent must necessarily have existed in the prior art reference. The fact that it was likely to be present is not sufficient. It is not required, however, that persons of ordinary skill in the art actually recognize or appreciate the inherent disclosure at the time the prior art was first known or used.

So, the prior art -- excuse me -- the prior use of the patented invention that was unrecognized and unappreciated can still result in an invalidating anticipation, provided the alleged inherent feature was

necessarily present in the reference.

As I noted, a printed publication can qualify as an anticipating prior art reference. In order to qualify as a printed publication for purposes of anticipation, a publication must have been maintained in some tangible form -- in this case prior to July 9th, 1996, which is one year before the application date of the patent -- somewhere in the world and it must have been reasonably accessible to that portion of the public that is interested in the subject matter of the '124 patent.

In other words, it is not enough that someone just wrote down his idea and never disseminated it or submitted it for publication or had it cataloged in a library. On the other hand, it is not necessary that the publication be widely known and available to every member of the public.

For these purposes, publications include not only books, periodicals, and newspapers but also publications that are not as widely available to the public, such as journal articles or scholarly papers that are normally distributed or available only to those working in the field of the invention.

However, a printed publication needs to be, for example, indexed or cataloged in a library or

otherwise made available so that a person interested in the art and exercising reasonable diligence who is searching for materials on the relevant topic would be able to find it. A printed publication is not prior art unless it can be found by the portion of the public that is most likely to use it.

To summarize on anticipation, if you find that Lilly has proved by clear and convincing evidence that claim 1 of the '124 patent was anticipated by some single prior art reference, then you must find in favor of Lilly on anticipation. But if you do not so find, you must decide in favor of UroPep on that issue.

Now we will move from anticipation to obviousness. Lilly contends that claim 1 of the '124 patent is invalid because the invention was obvious. To prove invalidity based on obviousness, Lilly has the burden of proving by clear and convincing evidence that claim 1 of the '124 patent would have been obvious to a person of ordinary skill in the art at the time of the invention.

Now, you've heard the term "person of ordinary skill in the art." It's a term, again, used frequently in patent law; and it has an important role in deciding whether an invention would have been obvious at the time it was invented. So, what does it mean.

A person of ordinary skill in the art is a person of average education and training in a particular field but who is aware of all the relevant prior art in that field. The level of ordinary skill in the art often depends on the nature of the field of the invention.

So, for example, if the invention is a way to generate additional energy in a nuclear power plant, the level of ordinary skill is likely to be significantly higher than if the invention is, let's say, a new way to fold cardboard boxes to make them stronger.

In this case the parties have agreed that a person of ordinary skill in the art, at the relevant time, which is 1997 when the patent was first applied for, would be a member of a drug development team with a graduate or postgraduate degree in one of the following fields: Anatomy, pathophysiology, biochemistry, medicinal chemistry, pharmaceutical sciences, or related scientific disciplines of urology and urologic surgery.

The drug development team could include analytical chemists, biochemists, clinicians, formulation scientists, and other related drug development scientists.

So, what does it mean to say that a patent claim would have been obvious to a person of skill in the art at the time of the invention? Unlike anticipation,

obviousness may be proved by considering more than one item of prior art and considering these multiple prior art references in combination.

For this purpose, you may consider whether there is anything that would have prompted a person of ordinary skill in the art to combine the elements or concepts in the prior art in the same way the invention does. But you also have to keep in mind that a patent claim that consists of several elements is not rendered obvious merely because each of the separate elements was known in the prior art.

For example, you could say that a piano is really just a combination of wood, ivory, metal and wires. But that does not mean that inventing the piano would be obvious if you just started with a pile of wood, some wire, some pieces of ivory, and a few chunks of metal.

If the claimed invention combined elements known in the prior art and the combination yielded results that would have been predictable to a person of ordinary skill in the art at the time of the invention, or the evidence shows that there was another reason to combine the elements in the prior art, that evidence would make it more likely that the claim is obvious.

On the other hand, if the combination of known

elements yielded unexpected or unpredictable results, or if the prior art would have led one to avoid combining the known elements, that evidence would make it more likely that the claim on the combination of those elements is not obvious.

In deciding obviousness, you must avoid using hindsight; that is, you should not consider what is known today or what was learned from the patent. You should not use the patent, in other words, as a roadmap for selecting and combining items of prior art. Instead, you must put yourselves in the shoes of a person of ordinary skill at the time the invention was made.

In determining whether claim 1 of the '124 patent would have been obvious, you should ask yourselves the following questions: What is the level of ordinary skill in the art? What is the scope and content of the prior art? What differences, if any, are there between the invention of the patent and the prior art? And, ultimately, the question you must decide is whether the invention would have been obvious to a person of ordinary skill in the art who was aware of all the prior art.

You also need to consider what are referred to as "objective considerations of nonobviousness."

Now, objective considerations -- objective indications are facts that may tend to suggest that the

invention was not obvious. For example, one objective indication, or consideration, that may shed light on whether the invention was obvious or not is whether a product that includes the invention was commercially successful as a result of the invention.

Commercial success will support nonobviousness if the success of the product is related to a feature of the patent claim in question. If the commercial success is the result of something else, such as marketing or advertising, and not the result of a patented feature, then you should not consider it to be an indicator of nonobviousness.

Other objective considerations or indications are, for example, whether the invention satisfied a long-felt need, whether others came up with the invention at about the same time, whether the invention achieved unexpected results, and whether persons of ordinary skill in the field praised the invention or expressed surprise regarding the invention.

Now, to summarize on obviousness, if you find by clear and convincing evidence that the invention set forth in claim 1 of the '124 patent would have been obvious, you must find in favor of Lilly. But if you do not so find, you must decide in favor of UroPep on that issue.

I'll turn next to two separate requirements that every patent must satisfy in order to be valid. They are known as the "written description" requirement and the "enablement" requirement.

Under patent law, the patent is required to contain a written description of the invention. The purpose of the written description requirement is to ensure that the person who files a patent application actually invented the claimed invention, and to keep people from seeking patents on things they haven't really invented.

For example, I could file an application for a patent claiming that I invented an electric car that goes a thousand miles before needing to be recharged. But unless my patent described my electric car in sufficient detail to make it clear that I have actually invented such a car, rather than just imagined that it would be nice to have such a vehicle, any patent I might get would be invalid because it lacks an adequate written description of the invention.

Now, Lilly contends that claim 1 of UroPep's '124 patent is invalid because the patent lacks an adequate written description of the invention of claim 1.

In order to succeed on its written description defense, Lilly must prove by clear and convincing

evidence that the patent fails to meet the law's requirement for a written description of the invention.

In deciding whether the patent satisfies the written description requirement, you must consider the written description in the patent from the viewpoint of a person of ordinary skill in the art at the time that the patent application was filed.

The written description requirement is satisfied if a person of ordinary skill reading the patent would have recognized that it describes the full scope of the invention that is claimed in the patent and that the inventor actually possessed the full scope of the invention as of the filing date of the patent.

Remember that a person of ordinary skill in the art has background knowledge that he or she will bring to reading the patent. You can consider that background knowledge because inventors do not need to put in their patents things that those working in the field already know.

For claim 1 of the '124 patent, the question of whether the written description requirement has been satisfied does not turn on whether UroPep was in possession of all PDE5 inhibitors. Rather, the question is whether the patent shows that the inventors were in possession of the invention that is the method of

administering an effective amount of a selective PDE5 inhibitor to treat BPH as of the priority date, or the date of the filing of the application for the patent, July 9th, 1997.

The written description requirement can be satisfied by any combination of the words, structures, figures, diagrams and formulas and so forth contained in the patent, as understood by a person of skill in the art.

It is not necessary to describe every compound used in the claimed method by name or structure in order to satisfy the written description requirement as applied to a group of compounds, as long as the patent includes a sufficient number of representative compounds or a common structural feature so that a person of ordinary skill in the art would understand, from reading the patent, that the inventor invented the full scope of the claimed method.

To summarize, if you find that Lilly has proved by clear and convincing evidence that the '124 patent lacks an adequate written description of claim 1, you must find the claim invalid. If you find that Lilly has not met its burden, you must find that the claim is not invalid for lack of an adequate written description.

Now, the other requirement I mentioned a

moment ago is the enablement requirement. To be valid, a patent must contain a description of the manner of making and using the invention that would enable a person of skill in the art to make and use the full scope of the invention without undue experimentation.

Lilly contends that claim 1 of the '124 patent is invalid because the patent does not contain a sufficiently full and clear description of how to make and use the full scope of the invention. In order to invalidate the '124 patent for lack of enablement, Lilly must prove by clear and convincing evidence that the '124 patent would not have enabled such a person to make or use the full scope of the invention.

In deciding whether a person of ordinary skill would have had to use more than a reasonable amount of effort or experimentation in order to make and use the full scope of the invention, you may consider several factors:

First, the time and cost of any necessary experimentation;

Second, how routine any necessary experimentation would be to make and use the method;

Third, whether the patent contains any specific working examples of the invention;

Fourth, the amount of guidance presented in

the patent to identify compounds within the scope of the claim;

Fifth, the nature and predictability of the field;

Sixth, the level of ordinary skill in the field; and

Seventh, the scope of the claimed invention.

A single factor does not necessarily decide that question. You should weigh those factors and determine whether or not, in the context of this invention and the state of the art at the time the original patent application was filed in July, 1997, a person of ordinary skill would need to use more than a reasonable amount of effort and experimentation to make and use the full scope of the claimed invention.

To summarize, if you find that Lilly has proved by clear and convincing evidence that the '124 patent lacks enablement or, to put it more simply, is not enabled, you must find the claim invalid. If you find that Lilly has not met its burden, then you must find that the claim is not invalid for lack of enablement.

Now, I am almost finished; so, we'll be done in just a couple of minutes. Let me get some water.

Thank you.

I'll next turn to damages.

If you find that Lilly has infringed claim 1 of the '124 patent and that the claim is not invalid, you must then decide the amount of money to award UroPep to compensate UroPep for the infringement. The legal term for that award of money is "damages," and I will use that term from here on out.

I will now instruct you on how to decide the proper measure of damages. By instructing you on damages, again, I am not suggesting which party should win this case. It is your task to decide, first, whether Lilly has induced infringement of claim 1 of the '124 patent and whether claim 1 is invalid.

If you find that Lilly has induced infringement of claim 1 and you do not find that claim 1 is invalid, then you must determine the amount of damages that are adequate to compensate UroPep for the infringement. UroPep has the burden to establish the amount of its damages by a preponderance of the evidence.

If you conclude that Lilly has infringed UroPep's patent, it will be necessary for you to determine the scope of that infringement in order to make a damages determination. That means you must determine how much infringement Lilly has caused.

For example, claim 1 extends only to acts of inducement that result in the treatment of BPH. So, if

you find that Lilly has induced infringement of the patent, you should only award damages for acts of administering Cialis, induced by Lilly, that were provided by a preponderance of the evidence to infringe claim 1 of the '124 patent.

A patent owner whose patent is infringed is entitled to what is called a "reasonable royalty" as damages for infringement. A patent owner is not required to make, use, sell, or offer to sell a product or process claimed in a patent in order to be entitled to at least a reasonable royalty to compensate for the infringement.

Now, a royalty is the amount of money that someone pays a patent owner to be allowed to use the patented invention. A reasonable royalty is often described as the amount of royalty payment that a reasonable patent holder and a reasonable infringer would have agreed to in a theoretical or hypothetical negotiation, had it taken place at the time the infringement began.

In considering that question, you should assume that both parties to the negotiation believed that the patent was valid and infringed and both were willing to enter into an agreement.

You are to decide what a reasonable royalty would be based on the circumstances in existence at the

time just before Lilly started to infringe the '124 patent by inducing infringement, that is, when Lilly learned of the '124 patent, which the parties have agreed was in October, 2014.

In deciding the amount to select as a reasonable royalty, you should consider the factors that UroPep and Lilly would have considered if they had been voluntarily trying to reach an agreement at the time the infringement began.

To do that, you should ask yourselves what amount of money a reasonable person would have paid for a license to manufacture, sell, and promote the use of the patented invention and still be able to make a reasonable profit, if that amount would have been acceptable to a reasonable patentee who was willing to grant a license.

Now, here are some of the factors you may want to consider in determining the amount of a reasonable royalty. These factors are listed in no particular order, and the significance of each factor is for you to decide.

First, expert opinions as to what would be a reasonable royalty;

Second, the royalties paid on similar licenses that either Lilly or UroPep have entered into in the past, together with differences in the circumstances of

those licenses that might suggest a different royalty rate in this case;

Third, the profitability of the products used in the infringing method and, in particular, the extent to which Lilly has made use of the invention and the value of that use to Lilly;

Fourth, the portion of any profit made by Lilly that is due to the patented invention itself;

Fifth, the extent to which Lilly, as a result of factors such as its marketing activities, has contributed to the success of the product;

Sixth, advantages of using the patented invention over products or processes not claimed in the invention that were available and could have been used to achieve similar results; and

Seventh, the commercial relationship between the parties, in this case the fact that Lilly and UroPep are not competitors.

No one factor decides the royalty amount. In addition to the factors I have just mentioned, you may want to consider whether other factors would have increased or decreased the royalty that Lilly would have been willing to pay and UroPep would have been willing to accept or any hypothetical party would have been willing to negotiate to reach agreement acting as reasonable

businesspeople.

Now, that concludes my instructions to you on the law. We'll take a break. But before we do, let me just tell you what will happen next, which is that the lawyers will present their closing arguments to you.

Mr. Hughes will go first for UroPep. Mr. Vital will then argue for Lilly. And then Mr. Hughes will have a chance to come back and make a final rebuttal argument for UroPep. After that, I will give you a few more housekeeping instructions, after which, the case will be in your hands.

So, let's take a break; and we will reassemble in about ten minutes.

(The jury exits the courtroom, 9:22 a.m.)

THE COURT: Okay. Counsel can set up.

(Recess, 9:23 a.m. to 9:32 a.m.)

(Open court, all parties present, jury present.)

THE COURT: Mr. Hughes, you may proceed.

MR. HUGHES: Thank you, Judge Bryson.

Good morning, ladies and gentlemen. This is my favorite part of the case. It's my last chance to get to speak with you, and I suspect it might be your favorite part of the case as your service is almost finished.

Before I get started, on behalf of Dr. Uckert, UroPep, the entire team here, we really do want to thank each and every one of you for your service and attention this week. I know we've covered a lot of complicated topics, a lot of science. Some topics were maybe more interesting than others, but we're grateful for your time and attention and we trust that you will be fair and you will be just.

When I first talked to you on Monday -- seems like a long time ago to me -- I talked to you about a simple rule and that simple rule is you don't go on someone else's property without permission. And I thought it was telling, interesting that not a single Eli Lilly witness came here and took the witness stand and said that they don't infringe. They never denied that they are using our property. They are on our property without permission.

We'll talk more about what that means in a moment, but I want to talk with you about another simple rule, a rule that I try to teach my boys, a rule that I try to live by. And that rule is when someone comes to you and says that you've wronged them, that they've got a problem, whether that person is big or small, powerful or weak, rich or poor, you have the common courtesy to sit down with them and try to resolve your differences.

What happened here is that UroPep, a team of doctors, scientists, medical researchers, were working on new therapies for diseases and they had a breakthrough. They came up with a new way to treat BPH. They went to the U.S. Patent Office and the Patent Office agreed, gave UroPep the '124 patent.

UroPep then went to Eli Lilly and said, "We've got this patent. You infringe it by using Cialis to treat BPH. Let's try to work this out. Let's try to do a deal out of court."

And when Eli Lilly received that letter in October of 2014 -- you've heard the evidence. It's not like we were strangers. It's not like UroPep was someone they had never heard of before. As you saw in the evidence, Eli Lilly, when they went to the FDA to get Cialis approved for BPH over and over and over again, cited the work of Dr. Uckert and the UroPep inventors.

And when Eli Lilly went to the Patent Office to try to get its BPH patent, the patent they never received, they cited one of our patent applications, the work of our guys, for the idea that using a PDE5 inhibitor is a way to treat prostatic diseases like BPH, the core of our invention.

So, they knew who we were, that we were real people who had made a real breakthrough; but they chose

not to respond. They chose to stonewall, to hope that we would never stand up for ourselves. But we decided to do just that so we came here to Marshall, Texas.

We talked about during jury selection that Marshall is a place that has a good reputation for patent cases, and we decided that Marshall was a place where a small team of scientists like UroPep could get a fair shake against a company like Eli Lilly.

One thing that I thought might happen this week is that Eli Lilly might bring a witness down here to explain why they never responded, why they kept infringing our patent, why they sold $700 million of Cialis using our property. But we got no such explanation.

We heard from three Eli Lilly witnesses: Dr. Viktrup, Dr. Sabo, and Ms. Hussain. They are all very nice people who came down here to testify for Eli Lilly as part of doing their job for the company, but none of them had seen the letter. None of them had any role in deciding whether or not to respond. In fact, none of them had even seen the patent until years after we decided to stand up for ourselves and bring a lawsuit.

So, instead of any explanation, what we were treated to was a list of excuses from expert witnesses who make their living defending pharmaceutical companies.

And I've got Eli Lilly's theory of the case here. The road is the road of UroPep, the road of Lilly's infringement. No one denied it. And that road leads to reasonable royalty and damages.

But Lilly doesn't want you to go down that road. They want to divert your attention, send you any which way they can. They've got the horny goat weed defense, obviousness, written description, enabled -- not enabled, every single way they say the Patent Office got it wrong.

And I predicted at the beginning of the case this is exactly what we would hear, the "yeah but" defenses. Yeah, we might infringe your patent but the Patent Office shouldn't have given it to you. They made a mistake. They got it wrong.

We'll talk about the problem with each of these diversions in a moment as we go through with you the evidence. I want to talk to you now about the issues that you're going to need to decide at the end of the case when you go back to deliberate.

And there are three of them -- Judge Bryson has instructed you -- infringement, invalidity and damages. And for the rest of my time with you this morning I'd like to walk through what the evidence shows on those issues. You just heard the jury instructions

from Judge Bryson and you'll have those back with you when you deliberate.

And we've worked -- the parties have worked with Judge Bryson to make those as understandable to you as possible, but they still include a discussion of legal terms that while we may all be familiar with them, you are probably hearing them for the first time.

So, I'll do my best to apply those legal concepts to the evidence to give you the tools that you need to answer those questions on the Verdict Form when you go back to deliberate this case.

So, let's start with the first question that you need to answer, and that is the question of infringement. Before I get into the evidence on that, I want to say a word about the burden of proof. The burden of proof on infringement is preponderance of the evidence. That means that we need to prove that it's a little bit more likely than not.

You see the scales of justice up there over there by Judge Bryson. The idea is that if you just put a feather on one side of those scales, that's what we need to do to prove infringement. But the evidence goes way beyond a feather. The evidence is overwhelming.

No Lilly witness denied infringement. Their own label, as we've been through many times during the

trial -- I don't need to repeat it -- shows that Cialis is a selective PDE5 inhibitor that is used in the treatment of BPH.

The one concept I did want to talk to you about which Judge Bryson instructed you on a moment ago is this concept of induced infringement. And, so, to prove induced infringement what we have to show is that someone carried out the acts that directly infringed claim 1.

And as you heard the evidence, the people who are administering -- there is that word "administering" in the claim -- those are the doctors who are prescribing Cialis. So, they are using the invention.

But we're not saying that the doctors did anything wrong. This isn't about them because it all starts with Lilly. Lilly knew about the patent. Lilly encouraged the doctors to administer Cialis to treat BPH with all of the advertising that we've talked about, the hundreds of millions of dollars, and their label.

And the last part, the third part, we have to prove that Lilly was aware of the patent and knew that encouraging doctors to prescribe Cialis for BPH infringed the patent. And we've done just that. They admit they knew about the patent in October of 2014.

And when I asked Dr. Sabo whether she had been

asked in October of 2014 whether Cialis was a PDE5 inhibitor used to treat BPH, she said she would give it an unqualified yes. So, there is no question they induce infringement.

The next set of issues you'll have to grapple with is whether or not -- back to the signs -- whether or not Eli Lilly has proved by clear and convincing evidence that claim 1 of the '124 patent is invalid.

We talked about the feather on the scale a moment ago for the standard of proof for infringement. The standard of proof for invalidity -- that's their burden, is clear and convincing evidence, a clear conviction, a strong belief that the patent is invalid, that the Patent Office got it wrong, that they made a mistake. And I submit to you that Lilly has not shown evidence that comes remotely close to invalidating the UroPep patent.

So, let's start with the first fork in the road. That's anticipation. I like to call it the horny goat weed defense. What anticipation is it's the idea Judge Bryson instructed you that a single reference -- in this case the Cheung document -- has to have each and every element of claim 1.

So, that document would have to show that a PDE5 inhibitor, the teeny little amount that is in horny

goat weed, was actually administered to a person with BPH and that it was that icariin, that little component of horny goat weed, that actually resulted in the treatment of BPH.

There is no evidence in this case to support that, because what happened is the expert that they brought in, Dr. Roehrborn, to testify about this, he testified that himself and the American Urological Association don't believe that horny goat weed, by itself, works. That's his opinion. That's the American Urological Association's opinion.

I'm showing you the testimony on the screen. So, they don't believe it works. There is no way they can ever get to clear and convincing evidence.

And then the other point to look at when you look at the Cheung reference -- and if you want some entertainment, you can flip through it in the jury room. What Cheung gave was this concoction of different things and we don't know what is in these plants. We don't know what is -- we don't know what might actually be causing any improvement in the conditions.

And remember they have to show that it is actually the icariin, the PDE5 inhibitor, that is causing any improvement. It can't be attributed to something else.

And Dr. Roehrborn admitted on the stand that he didn't know what would be causing the improvement, that it could be something else. That alone is sufficient to defeat their anticipation defense.

And finally, of course, Dr. Bell explained that because there is such a super small amount of this icariin in the horny goat weed that to ever get enough of it to have any chance of helping you, you'd have to eat pounds and pounds of it, which, of course, wasn't what the Cheung study does, and shows you just how little credibility this defense has.

Eli Lilly, a pharmaceutical company, sophisticated pharmaceutical company, brought in Dr. Roehrborn, who doesn't believe horny goat weed works, brought in an acupuncturist from San Francisco, paid him $280 an hour. This defense has no credibility, and you should judge all of their defenses based on that credibility.

Let's turn to the next issue, which is an issue of obviousness. Would it have been obvious in 1997 to a skilled person to administer a PDE5 inhibitor to treat BPH? Would they have figured out PDE5 is in the prostate? Would they have figured out PDE5 played a functional role.

And what Lilly says on this is that people

knew that PDE5 was in parts of the male urogenital system, the penis, the bladder, and people knew about the NO-cGMP pathway and that putting all those things together it would have been obvious to look to the prostate.

But this fails right out of the gate because Dr. Roehrborn admitted that the Patent Office had all that information. The Patent Office had information that we supplied them when we applied for our patent that PDE5 was in the penis.

They had information cited right in our patent. PDE5 was in the bladder. They knew about this NO-cGMP pathway that we heard so much about and they gave us our patent. They have the same information you have. There is no reason to second-guess it.

So, we don't have to go any further; but I'm going to, because something very interesting happened in this trial with Eli Lilly's witnesses on the subject of obviousness. And I want to make sure everybody understands what happened.

The first thing that happened is we heard from Dr. Roehrborn. He testified that it would have been obvious to use PDE5 inhibitors to treat BPH. But the interesting thing about Dr. Roehrborn is at the actual relevant time in 1997, he had no experience with PDEs.

And he admitted, as I told you, everyone would admit during this trial that there is not a single prior art reference, not one, that identifies the presence of PDE5 in the prostate or the functional role of PDE5 in the prostate. He admitted that.

And then he admitted that when he looked at the question -- when he looked at the question now, he already had the answer. He knew that PDE5 was in the prostate. He had a benefit that the people like Burnett and the other people writing in 1997 did not have.

So, he had an advantage. He had that hindsight bias. We all remember Mr. McBride's cross-examination. And none of those experts in 1997, the people who actually had PDE experience, figured it out. Judge Bryson instructed you, you can't use hindsight to judge the obviousness of the patent.

Next, we heard from Dr. Beavo. Now, Dr. Beavo is actually an expert in PDEs. Mr. Vare said he was the grandfather of PDEs. He'd been working on them long before 1997. But you know what we did not hear from Dr. Beavo? We did not hear an obviousness opinion. They didn't ask him if it was obvious, the qualified guy, probably because they wouldn't like the answer.

That brings us to Dr. Rotella. Dr. Rotella came to talk about how our patent wasn't enabled and

didn't have enough information for written description. He didn't offer an obviousness opinion on his direct examination.

But Mr. Mortara asked him about it during cross-examination for an important reason. Dr. Rotella was working at another pharmaceutical company in the mid-1990s, Bristol-Myers Squibb; and he and his team applied for a patent in 1998 on millions of PDE5 inhibitors, and they had a claim in that patent to treat 30-plus different diseases, everything they could think of. And do you know what wasn't in that list? BPH.

So, without the benefit of all the hindsight information, that team of experts, including Dr. Rotella, couldn't figure it out. They do not have an obviousness case. It does not come close to clear and convincing evidence, which brings us to the next couple of forks in the road: Written description and enablement.

The idea here is that we did not need to describe our claim -- or that we didn't describe our claim, that you couldn't use our invention, that it's super complicated, billions of compounds. But think about what Eli Lilly is saying here.

They are saying, on the one hand, that our invention is obvious; anyone could figure out how to do it; and then, on the other hand, that no one could figure

out how to do it because it is not enabled or that we didn't describe it or that you can do it with horny goat weed. These things don't add up. They are not consistent. They don't go together.

And drilling down a little bit more, the issue on enablement is pretty straightforward, and written description. We talked to Dr. Roehrborn about this. The experts at the Patent Office looked at this issue when we applied for our patent, and they determined that we satisfied the written description and enablement requirements. That's what they figured out.

We asked Dr. Roehrborn if he had any experience in looking at what's required in patents, if he had any experience figuring out the kind of information that you need to include in a patent to enable it, to provide written description. And he and Mr. McBride had that discussion about experience and how it takes 10,000 hours to become an expert.

The Patent Office are the experts. Dr. Roehrborn wasn't. There is no reason to second-guess the Patent Office on this issue.

But then we heard from Dr. Rotella on this issue. This is very important so I'll try to take it very slowly. He testified on direct -- Lilly put him on the witness stand.

He came to this court to tell you that our patent wasn't valid because we didn't include certain information in it. We didn't include in vitro information, information from the lab. We didn't include in vivo data, data about how PDEs might work -- PDE5 inhibitors might work in the human body. We didn't include all sorts of other data.

You heard some big words like "pharmacokinetic" and "half-life data." Those are all the criticisms he levels against our patent when he was on direct testimony on the witness stand.

But on cross-examination when Mr. Mortara talked to him and showed him his own patent, we learned something very interesting. He admitted that his own patent that he got at Bristol-Myers Squibb on millions of PDE5 inhibitor compounds when they had a claim to treat numerous different diseases -- ours is only from one -- he admitted that in his patent there was no quantitative in vitro data, no in vivo data, that that patent was missing all of the same things that he faulted our patent for.

And in his zeal to invalidate our patent -- we heard Mr. Mortara establish this -- he makes his living testifying for pharmaceutical companies. In his zeal to say that our intellectual property isn't valuable, that

our intellectual property shouldn't be respected, he admitted on the witness stand that his own patent might be invalid. That's what he admitted.

So, you can judge the credibility of their enablement and written description defense based on what Dr. Rotella admitted on the witness stand. We all remember the testimony. He didn't go back and tell the Patent Office. He didn't tell Bristol-Myers Squibb. He didn't tell anyone except us, for the first time on the witness stand, in his zeal to invalidate our patent.

The last thing I want to say about the issue of enablement is that we've heard a lot in this case about this idea of human clinical trials. We heard a lot of evidence from Eli Lilly about the clinical trials that Eli Lilly did when it went to the Patent Office to try to get approval for BPH -- for Cialis for BPH. And I just want to make sure that all of you understand what that is potentially relevant to and what it's not relevant to.

What it is not relevant to are these validity issues, the issues of enablement. Dr. Roehrborn admitted that human clinical studies are not needed; you don't need to put that information in your patent in order to enable it. Dr. Rotella certainly didn't in his.

And that -- to the extent it is relevant at all, to the extent that what Lilly did with human

clinical trials is relevant is that it could be potentially relevant to damages, but it is not relevant to enablement. That is the testimony of their own witness.

So I just want to make sure that that evidence is put in the proper context for all of you.

So, that brings us to the last issue that you're going to need to decide. That last issue is the issue of damages, what is a fair and reasonable royalty. We talked at the beginning of the case about the idea that there are some big numbers involved here.

When I talk to you at the end, I'm going to be asking you to award damages of $84.5 million. That's a big sum of money whether it's in Montana, whether it's here in Texas, anywhere. And I'm not going to be shy about that.

The issue is Cialis is a product that involves huge numbers and this invention that the UroPep inventors came up with goes to the core of one of the uses of that product that infringes our property.

And we've all seen the evidence. Billions of dollars brand-wide, huge profits. And even when you isolate it down to the infringing sales, the sales of Cialis after October of 2014 that were used to treat BPH, it's still a big number, $704 million.

And I want to just pause and make sure everybody remembers that the experts in this case agree, $704 million of infringing sales. That's what Dr. Vellturo calculated. He looked at the sales -- all the sales of 5-milligram one-a-day Cialis.

Then he took Lilly's own surveys of physicians and patients, surveys where those physicians and patients were asked, are you -- the patients, are you taking Cialis for BPH or BPH+ED? Physicians were asked, are you prescribing BPH to treat -- or prescribing Cialis to treat BPH or BPH plus ED? That was the evidence and he came up with 704 million.

And Mr. Jarosz -- I showed you this yesterday during his cross-examination. He used that 704 million right in his report. So, that's the starting point for both the experts. And Mr. Jarosz didn't get on the stand and say that that number should be less; so, I just want to make sure we are all on the same page.

So, the question then is: What is a reasonable royalty for these infringing sales? And Dr. Vellturo explained the logic. On these sales, Lilly made about a 30 percent profit. And he explained that since Lilly did all those human clinical trials and they developed the product and they spent the money on marketing, Lilly should get to keep more than half of

that product.

But he also explained that on the other hand, UroPep has an important invention. UroPep invented the idea of using a PDE5 inhibitor like Cialis to treat BPH. And UroPep has a right to keep Lilly from using that property without permission.

So, both sides have something important here, and Dr. Vellturo determined 12 percent would be fair and reasonable given the relative importance of UroPep's invention, which goes to a core indication of Cialis, versus Lilly's contribution.

And it really comes down to the benefits to Lilly of having that Cialis indication. And I talked about this yesterday a bit with Ms. Hussain. We looked at some of the data on those 5-milligram one-a-day sales of Cialis. That's when we had to go up there and talk about sealing exhibits, the financial information that we looked at.

And what we saw is, in October of 2011, once they got that approval for BPH, the sales went way up. They went on a rocket ship ride. And, again, I'll remind you, we're only claiming damages after October of 2014. This is evidence that just shows the before and after, before BPH and after, quantitative evidence on how important BPH indication is to Eli Lilly.

And the reasons for that are pretty simple. They are able to add new patients because of the BPH indication. They are able to take patients away from Viagra because it's not approved to treat BPH, so now doctors are switching away from Viagra, prescribing Cialis.

They are able to get insurance companies to cover more Cialis because insurance companies are more likely to cover a prescription for BPH than they are for erectile dysfunction. So, it's helped them grow their sales over and above the sales that they had before. That's why it's so important.

And we looked at all of the documents I went through with Mr. Jarosz during his cross-examination about how BPH was core, was critical to this "why pause" campaign. And I'm not up here suggesting that erectile dysfunction wasn't also important and hasn't always been important, but BPH was something new, something that gave them an advantage, something that gave them new sales. It was important. And that's why that puts the reasonableness of that 84 million in perspective.

The last point I would say about this here is that both the experts agree that Lilly has spent more than $300 million advertising Cialis for the treatment of BPH since October of 2014.

Again, they would not have been able to do that without using our invention. That's the infringement. That's how they induce the doctors and the patients to use. So, that again shows the core of that.

And I looked at this concept with -- on the "why pause" campaign, which started right at the key time, at the end of 2014, beginning of 2015. I looked at an exhibit -- I think it's D 1170, page 6 -- with Mr. Jarosz at the end of his cross-examination showing how much each month Lilly was spending on this "why pause" campaign that has both pieces -- 12, 14, 15 or more million dollars each month.

Again, they could not do that without the infringement, which puts the reasonableness of the royalty in perspective.

And then what we heard on the other side is we heard from Mr. Jarosz with his 1.9 percent royalty. I think his analysis makes no sense. He assumes that if Lilly took those approvals off the FDA label and quit advertising BPH -- he assumes that physicians would write hundreds of millions of dollars of off-label prescriptions and that insurance companies would just keep covering those prescriptions even though it is not on the label. He must have a different insurance company than I have because I don't think that would happen in

the real world.

And he assumed that the profits -- the infringing profits of Cialis would only be like 10 percent, when we know in the real world the profits of selling Cialis are way, way more than 10 percent. So, his analysis is hopelessly flawed.

I'm going to sit down now. I'm going to get a chance to talk to you again after Mr. Vital finishes his discussion with you; and when I get up, I'm going to talk to you about returning a verdict that shows intellectual property rights are valuable and that the patent rights of small teams of inventors like UroPep are just as important as they are for folks like Eli Lilly.

I look forward to speaking with you again shortly. Thank you.

THE COURT: Thank you, Mr. Hughes.

And Mr. Vital.

MR. VITAL: May I have moment, your Honor?

THE COURT: Yes.

MR. VITAL: Okay.

(The following proceedings were conducted at sidebar with all parties present.)

MR. VITAL: I apologize for the bench conference. I was looking for my notes, and I was sitting on them. But if I could have just a few minutes

to -- I'm going to have to set up the flip chart.

THE COURT: When you say a "few minutes," are you talking about two or ten?

MR. VITAL: If I could have at least five so -- a short break would be okay. I'd hate to shuffle around in front of the jury.

THE COURT: Okay.

MR. HUGHES: If we could do a stand and stretch, you know...

THE COURT: Let's do a stand and stretch. That seems to make more sense. Thank you.

MR. VITAL: That works.

(Sidebar conference concluded.)

THE COURT: Okay. Ladies and gentlemen of the jury, Mr. Vital is going to be getting set up for his closing arguments, so why don't we stand and stretch a little bit and we'll take a couple of minutes -- not long. But you can just limber up.

(Off the record, 10:00 a.m. to 10:04 a.m.)

THE COURT: Mr. Vital, you may proceed.

MR. VITAL: Thank you very kindly.

Good morning, ladies and gentlemen of the jury -- to be exact, six ladies and two gentlemen of the jury. I very much appreciate the opportunity to stand here and deliver a closing argument on behalf of Eli

Lilly and Company in a case that is very important, very important to Eli Lilly and Company.

On its behalf and for my own sake, I'd like to thank you because I've watched you all during the entire week. As I saw from time to time, y'all would look over and look at the -- various of the lawyers at the table. I appreciate that attention because I appreciate your time and I appreciate your service.

And the reason I say that, the reason I feel so passionately about what it is that I do for a living is that I believe in juries. I believe in what they stand for. I believe in your power. And that power does not come from Mr. Vital. That power does not come from Mr. Hughes. That power comes from the law.

And I mention that for a very important reason, because this case belongs to you. It don't belong to, in all due respect, even Judge Bryson.

I'm going to show you a Verdict Form. This Verdict Form is not filled out by Mr. Hughes. This Verdict Form is not filled out by Mr. Vital. This Verdict Form is not filled out by Dr. Uckert or, in all due respect, Ms. Hussain or his Honor. The Verdict Form is your decision, is your verdict. It is not the Patent Office's verdict. It belongs to you, members of the jury.

Mr. Hughes focused his argument on the Patent Office being the experts and trust the experts. I trust the jury. That's what I've been doing for a living for 20 years. I trust the jury. I trust the law.

The law is embodied in these Final Jury Instructions, the court's charge to you. You do not get your charge from the Patent Office; you get your charge from the judge. The judge tells you what the law is, and the law guides your decision.

So, as we make this argument, make no mistake about it. You get to make your own decision because the law gives us the protection, as it gives any United States citizen the protection or, frankly, any other person, to trust a jury to make something right, even if it's something the Patent Office did. If we were to trust the Patent Office and not trust the jury to follow the law as a checks and balance, we wouldn't be standing here.

So, with that backdrop, I'd like to cut to Mr. Slyter and talk about what I believe this case is about -- next slide -- an idea. Mr. Hughes and I agree on that. I agree with him on a lot of things. He's a -- I do this for a living, and he's a fine lawyer, and I love arguing cases to juries against fine lawyers. We agree on this point. This case is about an idea.

And Mr. Hughes, in his opening argument to you on Monday, said it right. I don't know if I agree with the word "new" so let me take that back. This is about an idea. And he claims and his client claims in this case that because they had an idea, they win this case. I want to talk about that in the context of patent law and the argument that you heard my colleague, Mr. Vare, make in opening argument.

Mr. Hughes talked about the fact that you don't step on somebody else's property without permission. And Mr. Vare responded, if you step on property that somebody claims is theirs but there is no notice, for instance, that's not fair and that's not right.

And that's partially why we have the law regarding some important concepts that we'll talk about, like written description and enablement, because a party cannot claim to own unlimited bounds of territory that they don't have, that they didn't describe, or that is not properly enabled. That's what the patent law requires.

Nor could a party claim ownership of an idea that was already in existence and being used. Nor can a party claim ownership to something that was obvious because it belongs to us all.

So, this diminishment, playing down, of the notion of obviousness cuts against the core of what you were asked to decide and the entire purpose of our patent system, which is to make sure that people do not claim ownership to things that they cannot claim ownership of.

And in that regard, I'd like to go to the first point I'd like to spend my time talking to you about in terms of what this case is about and why the idea is not enough by talking about obviousness, was the idea obvious.

Smart people. This is the defense: Smart people did not say, as of 1997, that PDE5 was in the prostate; so, therefore, it was not obvious.

I want to just say something just very simply. We have two separate defenses. In the patent system -- and these are not excuses, as Mr. Hughes said. We are entitled to assert these because the law gives us the right to do so; and they are appropriate in this case.

So, on behalf of my client, I will take offense -- they didn't say it, but I will take offense for them at the notion that we are not entitled to cloak ourselves in the law and ask you to make a decision that you are empowered to make. These are not excuses; this is the law.

And what the law says is you have anticipation

and obviousness. And I'll talk about anticipation in a second. But if you read the court's jury instructions, if it was stated, it would be anticipated.

And I'll talk about that separately because it was stated in the Cheung reference. So, it is anticipated. They just don't like the source that it's in because it's traditional Chinese medicine. And I'll talk about that in a second. So, it is anticipated.

But on a separate side, even if it's not anticipated, the law -- because if it was stated in a document, it would be anticipated. If it's not stated in a document, the question we ask is: Does the body of prior art provide a natural extension to the proposition that they claim is their idea.

And that's -- it's not whether people actually said it; it's whether the prior art -- and this is from the court's charge -- motivated or prompted somebody to make the next logical step.

You heard Mr. Vare talk about Burnett, Trial Exhibit Number 1245. It's an important reference because it is the extension that leads to that next logical step. It wasn't stated. But when you combine this reference with other references that you heard in the evidence -- and this reference alone, frankly -- was it obvious.

Let's see what this reference says. 1995,

before the patent-in-suit. Table 1, what was known? That in the penis you could cause smooth muscle relaxation to cause an erection. In the urethra we knew that there was this smooth muscle and it could be manipulated for micturition purposes, which is one of the signs and symptoms of BPH that we're talking about.

And in the same reference it talks about the prostate, that same smooth muscle that could be manipulated with respect to micturition. Through what means? It says, in the concluding paragraph, "through pharmacologic means."

I told you in jury selection I wasn't a big "size" person, but that's just a fancy way of saying medicine. Through some way that you could take to cause an effect.

So, if you look at this reference in 1997 and you're a smart person and you see a reference saying we should look at some pharmacologic agent or medicine to cause an effect, what type of medicine might that be? It would be something that would cause smooth muscle relaxation.

And what we know, in addition to alpha blockers in the prostate, is that smooth muscle relaxation -- you heard from the evidence -- Dr. Roehrborn stated it and it did not go credibly

rebutted because it is a true statement -- that you can manipulate smooth muscle relaxation through PDE5 inhibitors if you know that there is cGMP present, which we knew.

Let me go through the slide that we just created in this courtroom this morning, Mr. Slyter.

So, during Mr. Hughes' argument I asked Mr. Slyter to put the slide together -- you may have seen me leaning over to whisper to him -- because it occurred to me that if we knew -- and the right side is the Burnett reference.

If we knew about smooth muscle relaxation in the urethra and if we knew about smooth muscle relaxation in the penis and even though there is a question about whether PDE5 was functional in the bladder -- we'll give them that. I think it was, and I think the evidence shows it.

But the question is: Would a smart person skilled in the art in 1997, putting all of these puzzle pieces together, have thought, hmm, the penis and the bladder have a gland in between them in the same system, the urogenital system? Maybe we should look there.

We know it has smooth muscle in it. We know these other organs around it have PDE5. We know about these PDE5 inhibitors which are pharmacologic agents to

cause a reaction based upon Burnett. So, maybe we should look for it there.

That's what they claim is their obvious -- their invention. I slipped. I said "obvious," because it is obvious. Look at it. It is right there in front of you.

That's why you have the power to speak, to look at the references, to follow the law, to make the next logical extension or step and come to the conclusion, maybe we ought to look for it in the prostate. And that's what Dr. Uckert and the inventors did.

Let's go back to the slide deck, and let's go to the next slide.

The evidence also showed, through the testimony of Dr. Bell, that there were other companies in this area in the same timeframe. Understand that these are smart people who all know each other and are aware of each other.

Dr. Andrew Bell, from the witness stand, said -- and you know he worked for Pfizer -- said that Pfizer scientists began looking at sildenafil to treat BPH.

Let me pause here for a second.

What is sildenafil? Viagra. What is Viagra?

A PDE5 inhibitor. What is BPH? Benign prostatic hyperplasia.

So, here is another group of scientists -- and you see his answer. He's anchoring it or referencing it to 1997, doing work and looking at the same thing in the same timeframe. Because of Burnett references and everything else, it's obvious. People are looking at it.

Maybe we can manipulate the effects -- maybe we can manipulate and have an effect on smooth muscle to loosen up that smooth muscle and allow the man's urine -- or, as Dr. Viktrup said, "voiding" -- to happen more smoothly.

And if we'll go to the next slide.

In the same timeframe -- and granted, it's here in 2001. But let me pause for a moment and ask you if you will recall Trial Exhibit Number 1011. I hope it's in your notes, but I'll call it to your attention right now.

Trial Exhibit Number 1011 is a slide deck from the science and technology committee of Eli Lilly and Company. Slide Number 6, Bullet Point Number 2 talks about why Eli Lilly and Company was interested in the ICOS partnership and investing in the partnership.

And what they saw was the value of tadalafil, a PDE5 inhibitor like Viagra, to cause smooth muscle

relaxation. It's right there in the slide, 1998.

So, you had 1997 activity. We've got 1998 activity. This is all around the same time because Burnett and Takeda have spoken. They have written and everybody is looking at the literature and they are all arriving at the same obvious conclusion.

And launching from Trial Exhibit Number 1011, the 1998 document, three years later, considering the entire life cycle of the drug as you heard Dr. Sabo say, the extension was, where else can we have this smooth muscle relaxation effect in the body; and we stated our own rationale for a PDE5 inhibitor.

And I laugh because Mr. -- we work a lot together. I like Mr. Vare. I like him a lot. He's very passionate and he said -- because it was right. He said you're going to hear Dr. Burnett a whole lot; because it's very important, because Burnett is establishing a principle from which everybody else is making an obvious conclusion.

And we stated our rationale based upon his work that we could reinforce the NO-cGMP signaling pathway with a PDE5 inhibitor to induce smooth muscle relaxation leading to the relief of BPH symptoms.

That's what Pfizer was looking at, based upon Dr. Bell. That's what these scientists for UroPep talked

about in 1997. And it's all based upon the same set of scientific literature. Doesn't belong to anybody.

And that's the beauty of the power that you have. You are allowed to announce to the world that we, the jury, agree that the body of scientific literature establishes that it was obvious and you cannot claim ownership to an obvious idea.

That's all the evidence says. That's all it leads you to. And the relevant language is, would a person have been prompted to do it, and I've shown you they were prompted to do it -- I'll give them credit for that. They were prompted to do it, as were other people because it was an obvious extension.

So they cannot own it. And you have the power to tell the Patent Office that you sat in a long trial in Marshall, Texas, and you heard the experts speak and you saw the evidence and you disagree. You have that power. And the evidence, I believe, compels you to make that decision.

I would like to next move to anticipation. This is a separate defense. Remember I said, if a reference had said PDE5 was in the prostate and it was functional, then that would be anticipation. So, obviousness says it was not stated, but would it have been a logical extension? Yes, obvious.

Next defense. If it's anticipated, meaning it is not new, just like you can't claim ownership of an obvious idea, Mr. Hughes' client cannot hold my client, stick them up with the October 2014 letter because the Patent Office got it wrong -- which they do; otherwise, we wouldn't have the law that we have. They can't stick us up for something that is anticipated.

How do we know it's anticipated? Because it was stated within the four corners of one document. That's Victor Vital's rendition of what the law says. But the judge told you and it's in here. And what is that one document? It's the Cheung reference, Trial Exhibit Number 1551.

What I believe to be one of the most moving parts of the trial was when Dr. LaForgia testified about the Cheung reference. I have a copy of it. It's here on the screen in electronic form. But he had the original from 1994. That's an important date because 1994 comes before 1997.

And if somebody said something in a reference before 1997 -- I see you smiling -- it ain't new. It's not new. That's why they want to make fun of it. They want to make fun of it and denigrate it because they know it's not new.

The jury charge talks -- the jury instructions

talk about a person who was interested in the art. So, the question is, was this document otherwise available prior to 1997 by someone who was interested in the art. Who was interested in the art? The art is this whole notion and business about BPH.

How, do we know that someone interested in the art was interested in it and had access to it? Because Brian LaForgia asked Dr. Cheung to write this because he had patients who were having these symptoms.

And let me pause here for a moment. We have a slide on this, but I've got to talk about this. The AUA has their own guidelines and they do not officially recognize phytotherapy or herbal supplements.

Doesn't mean you can't go to Whole Foods and buy them or Tom Thumb or wherever you want to buy them from. They just do not at the time -- and we'll talk about that in a moment -- say that they themselves officially prescribe them, which kind of makes sense. It's kind of obvious. They are over the counter. You don't need a doctor to prescribe plant therapy. You can go to Whole Foods or some herbal supplement store and buy your own.

So, this notion or business that Dr. Roehrborn does not acknowledge that the AUA does not make it official does not mean that it doesn't exist. It's what

we call in law a "strawman" or argument or debate. It's a strawman. It's a false argument. Doesn't matter what the AUA believes. But we'll talk about that in a moment. It matters what the Cheung reference showed.

But what does the AUA say, in fact.

We'll go to the next slide.

This is Trial Exhibit -- Plaintiff's Exhibit Number 265. This is the AUA -- which is the association for the urologists like Dr. Sliwinski, Dr. Roehrborn. If they weren't interested in it, if it wasn't on their radar screen, it wouldn't be in their guidelines.

They are recognizing that nonconventional approaches exist and have been of great interest for many years. It's been of interest to traditional Chinese medicine and they are looking at it.

So, just because the fancy urologists -- and I like Claus Roehrborn -- Dr. Roehrborn a whole lot and his AUA association. But the bottom line is, they do not get to judge what is anticipated. Just because they, at this time, didn't officially recognize it, it doesn't mean it didn't exist.

But even they recognize it and it has been of interest for many years and they are studying it. They even acknowledge that higher quality evidence has begun to appear and the assessments of efficacy are beginning

to evolve. Those are fancy words for --

Next slide, please.

-- the fact that they recognize that this can actually work, which means it is anticipated. And I'm going to show you that it does anticipate. Here is the claim, a method for treating benign prostatic hyperplasia. Is that what this is about? Yes.

Next slide.

Administering to a man -- or person in need -- an effective amount of a PDE5 inhibitor, icariin is in there, and it's a selective PDE5 inhibitor.

Let's go to the next slide.

The formula set out in pages 80 and 81 of Trial Exhibit Number 1551 tell you that the ingredient includes icariin --

Next slide.

-- which is why it's working. This is not rocket science. It's not rocket science at all. We know that selective PDE5 inhibitors work to induce smooth muscle relaxation causing men relief from BPH.

That's what this whole trial was about. They just don't like the fact that there was a reference that existed before their claimed invention that said the same thing, that did the same thing.

And we know it worked because it had a 94

percent success rate. That's pretty good to me. That would mean you got an A in school. So, icariin got an A. That's just plain -- I like to be plainly spoken. It got an A.

94 percent of people who showed up in this study had relief. And we know they had relief because they were supposed to get relief. Why were they supposed to get relief? Because icariin said so. Icariin is a PDE5 inhibitor and it's supposed to work and it does work.

Next slide.

Now, this whole notion about this slide -- you know, it's a really misleading slide. It really is. The claim doesn't require it to be equal to a potency of tadalafil. That's our own unique structure. It belongs to us. And it is powerful. But just because it's more powerful than other PDE5 inhibitors doesn't mean that the other PDE5 inhibitors are not PDE5 inhibitors that are selective under the court's definition.

Next slide.

I would like you to remember this document and take this back with respect to icariin, Defendant's Exhibit 1328. Exhibit 1328 gives you a better comparison, not the misleading comparison they wanted to leave you with. It compares zaprinast, which is in the

'124 patent, to icariin. And what does it show? They are roughly similar. They are roughly similar.

So, I just kind of winged it last night and put together this slide just to give you an impression of what a true comparison could possibly look like. If you compare zaprinast to icariin and then you want to know what the amount is, you don't have to eat pounds of it. It's going to be a smaller amount.

You can manipulate the result to try to make fun of our reference that existed in traditional Chinese medicine by giving a false comparison, but if you look at zaprinast, which is in the patent, you don't have the big stack, the 3 pounds.

And we know it works, as I close this argument, because 94 percent of men taking epimedii, which is horny goat weed, which includes icariin, got relief.

Now I'd like to move to written description -- oh, before we get to written description, let's back up and I want to go outside of the presentation and play a clip. This is from Dr. Terrett, the independent expert in this case.

(Testimony presented by video.)

Question: In 1997, would a person of skill in the art understand that there was a single common

chemical structure or feature for all inhibitors of enzymes?

Answer: No. Inhibitors are very diverse in their structures.

Question: In 1997, would a person of skill in the art understand or know of a common chemical structure or feature for all inhibitors of PDEs?

Answer: No. The structures that inhibit PDEs are, again, structurally very diverse.

Question: In 1997, would a person of skill in the art understand or know of a common chemical structure or feature for all inhibitors of PDE5?

Answer: No. The PDE5 inhibitors, again, represent a fairly diverse collection of different chemical structures.

(End of video testimony.)

MR. VITAL: That is important because of page 16 of the jury charge talking about written description, which is the third defense that the law entitles us to cloak ourselves in and to use as protection. You cannot claim ownership of an idea that you did not adequately describe. If I don't know the bounds of what the property is, how fair is that to charge me? It's not fair at all.

And we have a defense called "written

description." And that's what Dr. Terrett basically just testified to. "The patent has to include a sufficient number of representative compounds or a common structural feature."

What you just heard is that that doesn't exist and it can't exist. And you can't feel sorry for UroPep because they can't meet the burden or they didn't meet the burden. They listed so few compounds in the patent they cannot meet the standard enunciated by the court, set forth by the court in the jury instructions, based upon what Dr. Terrett just said. They fail big-time.

And not only do they fail under the written description requirement under the testimony that you just heard right here in closing argument, but they also fail on enablement.

You can have an idea -- this is the fourth defense. But if that idea is not enabled, you can't claim ownership to it and you shouldn't have gotten a patent for it. People have been talking about flying, for instance, for many years going back centuries. But just because you had the idea, if you didn't enable it, show how somebody who wanted to use it could work it, it's not enabled.

Next slide.

So, there are factors that talk about whether

something is enabled, and these are the factors and they are in the jury instructions. I want to show you, for instance, how one of them works, "working examples in the patent."

Are there working examples in the patent? It talks about injecting yourself, as you heard from testimony, six to seven times a day. Is that working? I don't think so. Who wants to do that? That's not working. That don't make sense.

"Topical administration," that means to put something on your skin like ointment if you have a rash. How do you topically -- how do you put something on your body to induce smooth muscle relaxation? You cut somebody open and go inside and put it on -- that just doesn't make any sense. It's not a working example. Just one factor that they failed.

Next slide.

"Scope of the claimed invention." You have to consider the scope to consider whether they gave enough enablement to use the invention. And we know the scope is huge, billions and billions, based upon Dr. Uckert's testimony. Confirmed by Dr. Terrett, whose audio we're not going to play, for the sake of time, but you'll remember.

Go to the next slide, Keith.

(Video presentation to the jury.)

MR. VITAL: Let's stop there.

He told you that we're talking about billions. Again, we're talking about billions. And why is that important.

Next slide.

Because just for one class of compounds, quinazoline, we got billions.

Let's just move through the slides until we get to 500.

This is just one class of compounds. And that's just 500 derivative molecules and we're talking about billions within that class alone, just that class. So, we're talking about an immense universe that you have to instruct or enable people interested in using the invention how to use it.

Next slide.

(Testimony presented by video.)

Question: Let's go to Column 2 of the '124 patent.

Beginning in Column 2 around line 28, do you see that, where it starts, "preferred selective inhibitors of PDE1, 4, and 5 are..."

Answer: Yeah.

Question: And do you know why that list of

compounds with letters a) through j) are identified as preferred selective inhibitors of PDE1, 4, and 5 in the '124 patent?

Answer: No. I don't know.

Question: Do you know who selected those compounds?

Answer: I don't know.

Question: You did not select those compounds --

Answer: I did --

Question: -- of preferred --

Answer: I did --

Question: -- inhibitors?

Answer: I did not -- I did not make this selection.

(End of video testimony.)

MR. VITAL: Let's stop there.

Patent guidance, that's another factor. You've got a broad scope, billions and billions and billions, and the named inventors are telling you in this courtroom, that we just heard again, that he doesn't know why the examples in the patent selected as preferred selective inhibitors were included. That's not providing any help to anybody who is interested.

Let's go to the next slide and beyond that

slide.

Question: Would all inhibitors of PDE5 work to treat or prophylactic BPH?

Answer: It's impossible to say.

Why is that important? We're talking about billions. They give no guidance for why they included what they included in the patent. And Dr. Terrett, who is Dr. Bell's boss at Pfizer, basically just told you that you don't know -- it's impossible to say what will work.

So, if it's impossible to say with billions and billions, you've got to provide a whole lot more guidance than the eight-column patent that got approved by the Patent Office. You have the power to say this is not enabled.

Next slide.

And we heard from Dr. Beavo who told you about -- I call -- it talked about the pig, the pig paper. That's the Truss paper. I just call it the pig paper so I can remember it. It's the Truss paper.

The grandfather of PDEs basically told you -- separately from the fact that we heard that we don't know what will work and how it will work and how to make it work -- you just heard that -- they got a paper that doesn't work and the grandfather of PDEs told you that.

The patent is pockmarked with problems regarding whether it will work and how to make it work regarding this immense scope of the claim.

May I have the ELMO, please.

That's important because Dr. Bell testified and confirmed that with respect to the compounds that will inhibit, he couldn't tell you which ones could be administered in an effective amount to treat BPH. The patent doesn't tell you. It doesn't say which ones.

And that's important because on Mr. Mortara's examination, final examination of Dr. Bell, asking about this method -- they want to say it is just a method, but you can't practice the method without the compounds.

This is what Dr. Bell said.

"Is it just the compounds that were known? Is it just the compounds in the patent."

This is one of the final answers in the case, which is why I love it so much: "It covered both," those that were known and those that were brand-new, billions and billions and billions. So, if it covered both and there are billions and billions and billions of possibilities and we don't know which ones will work and we are not told how they will work, this is not enabled.

Next slide.

And if we can animate this slide.

You will remember as it animates that Dr. Bell told you he had a project at Pfizer, this is Trial Exhibit Number 1598. Starting with 500,000 compounds, five years of work, with way more guidance, that's in the patent. Set of key criteria designed to give confidence. And how many worked? None.

So, even these criteria did not generate a suitable compound of this diverse set of PDE5 inhibitors that we know it's impossible to say if they would work. If this is not enough, you know that what's in the patent is not enough.

And now I'd like to go to what Eli Lilly and Company did. Based upon an entire universe of billions and billions and billions, based upon hard work that the company did that you heard about -- you saw the stacks of documents -- we found a selective PDE5 inhibitor that would work; and we put it on the market. And we are here today asking you not to let this company get held up in this courtroom.

You heard Mr. Jarosz say that it's not fair to try to hold somebody up. That's not the way you do patent damages. You don't hold somebody up based upon the work they did when you don't own the property. You send me a letter. You tell me you want me to pay you for standing on my own property? What kind of sense does

that make.

What if I said I want you to pay me millions of dollars because you are standing on your property that you have the right to be on under patent law because it belongs to us all? You can't claim ownership to that. You can't charge Victor for standing on his own property. That's why we didn't respond to that letter. The company is offended by that letter because of work we did, because of what we are entitled to rely on under the patent law. That's why we are proud to stand in this courtroom to say you are our only protection, only protection.

As I leave you, as you fill out the Verdict Form, you are our only protection, as you answer the questions that are in the court's charge, to prevent us from being held up by this plaintiff. So, I'm going to ask you -- I'm not going to talk about infringement. I'll leave that to your sound discretion. Did they prove an enlarged prostate? I'll leave that to you.

I want to talk about enablement. I want to talk about invalidity. You're going to answer yes to all of these questions here because the law allows us to a yes answer and you are entitled to protect us.

THE COURT: Mr. Vital.

MR. VITAL: Thank you very kindly.

And the damages question you heard Mr. Jarosz say, $11 million, is more than they deserve. We don't think they deserve anything. We will leave that to your sound discretion. Don't let us get held up today. We appreciate your time.

Thank you.

THE COURT: Thank you, Mr. Vital.

Mr. Hughes, you have rebuttal.

MR. HUGHES: May I have one minute, your Honor, to gear over?

THE COURT: Yes, you may.

MS. SMITH: Ms. Greenwald, do I have 18 minutes?

LAW CLERK: Exactly.

MR. HUGHES: Your Honor, may I proceed?

THE COURT: Please do.

MR. HUGHES: I've only got a few minutes left to speak with you, and I'm not going to be able to respond to everything that Mr. Vital said. You've heard a lot of testimony on each of these issues. But let me try to hit the high points for you now that it is clear that really what Lilly is doing is focusing on every single one of their different arguments for why the patent is invalid.

And, again, I'll remind you as we go into

these that the standard of proof on each of these is a clear conviction, a strong belief that the Patent Office got it wrong.

Mr. Vital is right. That is a question for you as the jury to answer. You have that power, and we want you to exercise it. But I want to go through the evidence and show you how Lilly has come utterly short in satisfying their burden of proof.

I'll start where Mr. Vital started, on obviousness. And I'm showing you what he showed you, which is the Burnett article. I want to make sure that there are a couple of things that are crystal-clear. Burnett was an author who was writing in this area at the key time.

Do you know what Burnett never figured out, what he never wrote in any article? He never wrote that PDE5 was in the prostate. Never once. That's all the hindsight bias of their expert. What this article is about is about nitric oxide. It doesn't say anything about PDEs and the prostate, and it's got question marks and so forth all over it.

There has also been some testimony, Mr. Vital point out, the urethra. There hasn't been any evidence in the case that that was known before 1997. And as I explained to you already, the Patent Office had this

information. We told them that PDE5 was in the penis. We told the Patent Office that it was in the bladder. And the Patent Office determined that even in light of all of that, it was a new invention.

And the evidence in the case that confirms that, that confirms that UroPep and Dr. Uckert came up with something new is Dr. Rotella: Dr. Rotella is on a team at a pharmaceutical company with a big group of researchers and they are trying to figure out how to use a patent that covers millions of PDE5 inhibitor compounds in 1995 to treat every disease. They listed like 30. Mr. Mortara stood up here and read them all to you. And the one that was not on the list is treating BPH.

There is no way that they can overcome the clear and convincing evidence requirement in light of the fact that we know that a team of medical researchers who were looking at this at the time didn't figure it out.

And Mr. Vital also showed you some testimony from our witness, Dr. Bell, where he was asked about BPH. But his answer was about high blood pressure, hypertension. So, I just wanted to make sure you saw that on the screen.

And the last point that I'll make on here is that Dr. Roehrborn's testimony was pretty compelling. He admitted he had the answer when he went to look at this

question. He's the guy who sponsored the obviousness opinion. He's their expert who said it would have been obvious. He didn't know anything about PDEs in 1997. He had the answer when Lilly asked him to look at it today.

And the guys who were writing at the time -- Burnett, Takeda, all these folks they want to talk about -- they didn't have the answer. They didn't figure it out. It's the ultimate hindsight bias case.

And I want to point out to you that in the obviousness instructions, the jury instructions that Judge Bryson read to you, it provides, page 13: "In deciding obviousness you must avoid using hindsight; that is, you should not consider what is known today or what was learned from the patent. You should not use the patent as a roadmap for selecting and combining items of prior art. Instead, you must put yourself in the shoes of a person of ordinary skill in the art at the time of the invention."

And we know what people in those shoes did. They didn't figure it out. That's Dr. Rotella and his team at Bristol-Myers Squibb. That's all of these authors. They do not have clear and convincing evidence on this issue.

Next is the issue of anticipation, the Cheung reference. I'd like to put that up on the screen and

make a couple things clear.

This is what they are relying on to say that Cheung anticipates claim 1 of the '124 patent. And what they have to prove in order to show that is that this herbal epimedii that I've got highlighted here was actually administered to a patient. There is a question on that because there is an "or" on here so we don't even know if that happened.

And then they have to prove that the icariin, which is just a tiny component of the herbal epimedii, was what actually helped these guys as opposed to all of the other things on this list.

And Dr. Roehrborn testified -- he's the only witness that sponsored this opinion. He testified he didn't know. He didn't know whether it was these other compounds versus the icariin.

And Mr. Vital showed you some things from the American Urological Association. I want to just put those in context. I'll show you what he showed you. This has nothing to do, zero, with horny goat weed. It is about saw palmetto and stinging nettle.

The recent studies -- I see down here in the lower right -- failed to confirm that there is any way these even worked. It has nothing to do with it. No way they have clear and convincing evidence on this question.

And then Mr. Vital showed you a slide that he made about icariin and zaprinast and made fun of our slide with all the weed in it. But what he didn't explain to you is that icariin is a tiny, tiny component of horny goat weed.

What his slide is, is comparing if you take that icariin out and compare it to zaprinast, then you can have the kind of comparison he did. What we are talking about is that icariin is just a teeny, teeny amount of that horny goat weed. And Dr. Bell testified you would have to consume a massive amount in order to anticipate.

There is no way this comes to the clear and convincing evidence standard that is required for you to find that the '124 patent is not valid.

And, in fact, I just want to -- I want to show you what Mr. Vital showed you because I've got a little time. This is what he showed you. He is showing you a comparison of the extracted icariin and zaprinast. He's not showing you a comparison of the horny goat weed to zaprinast. That's what Dr. Bell did. He said how much horny goat weed would you have to consume.

So, again, they don't have the clear and convincing evidence on the issue of anticipation.

Then we come to the concept of written

description. And here, again, the Patent Office has looked at this issue. Dr. Bell explained that the idea is that someone with skill in the art -- remember the instructions instruct you you've got to look at these issues from the perspective of a person of ordinary skill in the art.

So, that is somebody who, in 1997, was a member of a research team with medicinal chemists, urologists. That's why we have to have these experts come in here and talk to us about whether or not these issues are satisfied. So, you've got to put yourselves in those shoes.

And Dr. Bell testified that you bring to the table everything that is known in the art. We don't have to copy and paste it into the patent.

And what was known in 1997 in the areas of PDE5 -- we talked about this during the trial -- PDE5s were already in clinical trials with Viagra and sildenafil. Zaprinast was in clinical trials. These were known drugs. These were known category of drugs or compounds and they were published in the literature. There were many of them known. You heard Dr. Bell's testimony.

What our patent is, is the idea of using that known class of compounds in order to treat a new disease.

That's what we invented. That's what we came up with. And that's exactly what our patent describes.

And Mr. Vital focused on this language in the jury instructions on page 16 about "a sufficient number of representative compounds or a common structural feature"; it's one or the other. And there are representative compounds in the patent.

You heard from Dr. Bell about it's got sildenafil; it's got zaprinast; it's got selective PDE5 inhibitors. Those are enough for a person like Dr. Bell, a skilled person, to figure out the scope of the claimed invention.

And then in terms of common structural features, I think you all heard the testimony from Dr. Bell yesterday about the common structural feature of the frog example.

So, there is more than sufficient evidence to support written description. They don't have the evidence to get them over the clear and convincing hurdle that they would have to satisfy.

And, again, recall the testimony of Dr. Roehrborn. He didn't have the experience about what needs to be in the patent. The Patent Office had that experience. They had this information. They looked at the information you have, and they decided that the

patent was valid and issued it to UroPep.

The last issue that Mr. Vital talked about is enablement, and that's really the idea of how much information do you have to put in these patents in order to permit somebody of skill in the art -- it's not you or me or Mr. McBride picking up the patent and saying, "Well, sure, now I can use it." It's somebody who is actually an expert practicing in that field. And, again, that person brings all the tools to the table that are known at the time.

So, the question is: What kind of data, what kind of information do you have to put in the patent in order to enable the patent.

And, again, the testimony of Dr. Rotella is important here because he testified that all of the criticisms that are being leveled at our patent, because it covers a lot of compounds and it's only got certain data in it, apply equally to his patent that he got with Bristol-Myers Squibb.

And that just undermines all of their claim about enablement in this case, and it shows you that these kind of patents frequently do cover millions of compounds, lots of compounds. And Dr. Bell explained that the experts have the tools and the resources available to test those, figure out which ones work and

move forward and practice the invention.

And that's exactly what's happened here. There is no question that Lilly is using the invention. Lilly is using the invention by selling Cialis to treat people with BPH.

I want to go through now the Verdict Form with you. I'll go through the questions that you'll need to answer. The first one, I think there is no longer any dispute. Mr. Vital didn't get up here and say that there is no infringement.

So, question 1, has UroPep proved by a preponderance of the evidence that Lilly induced infringement of claim 1 of the '124 patent? That's an easy one for you-all. The answer is yes.

The next question you'll need to answer, "Has Lilly proved, by clear and convincing evidence, that claim 1 of the '124 patent is invalid for any of the following reasons."

We have just walked through all of those. They don't have credible evidence. They can't get over the hump on "clear and convincing," "firm belief." They don't even come close. So, the answer to each of those is "no."

I don't even really hear them defending the damages issue in any meaningful way anymore. BPH is

super valuable to Lilly. Dr. Vellturo conducted that analysis. We talked about the value when I spoke with you earlier.

And, again, this is a big number, but it's leaving, you know, more than half with Lilly. They get to keep the lion's share of the profits. This is a reasonable royalty Dr. Vellturo calculated and we talked about in the trial. You heard the evidence.

Now, Mr. Vital talked about the power of a jury and how this case is in your hands. And it is about to be in your hands; and, again, we thank you and appreciate your service and we respect your power and we respect the verdict that you will return.

And for the first time from Mr. Vital we heard Eli Lilly's outside lawyer finally give an explanation for why they never responded to the letter, that they don't think it's valid for the host of different reasons that we've talked about today.

But Lilly didn't send anybody down from Indianapolis to give an explanation during the trial. Instead, those executives stayed there waiting to see if their strategy of never responding to UroPep would pay off, of stonewalling, of not being willing to sit down with us and try to work it out.

And, so, now the case is about to go into your

hands, and it is up to you to decide if Lilly's strategy is going to pay off. It's up to you to give Dr. Uckert the response that Lilly never provided, that his work and the work of the UroPep inventors mattered, the work that was cited over and over again by Lilly, the work that was cited by Lilly to the Patent Office.

Did he and UroPep make a valuable contribution? You get to decide whether Dr. Uckert and the inventors at UroPep invented something, made a valuable contribution. And you get to judge the credibility of Lilly's criticisms of this patent with their experts in court with their out-of-court conduct where they are citing our inventors over and over and over again to the FDA, where they are citing one of our patent applications in their own failed BPH patent application to the U.S. Patent Office. You can decide the credibility of Lilly's position based on that evidence.

It is really up to you to decide if the intellectual property rights of small teams, small teams of scientists working at medical schools are valuable and are as valued as the intellectual property rights of companies like Eli Lilly.

I hope that after the verdict, Lilly will understand that there aren't two rules here. There is

not one rule for Dr. Uckert and the UroPep inventors and one rule for Lilly and their patents. The rules are the same.

We have valuable intellectual property rights. Lilly has been on our property without permission since October of 2014. No one disputes they have infringed to the tune of $700 million, and I respectfully submit that the right verdict is a verdict of infringement, that the patent is valid, and that damages are $84.5 million.

Thank you very much.

THE COURT: Thank you, Mr. Hughes.

Jurors, it is now time for you to deliberate on your verdict. The first thing you should do when you retire to the jury room is to select a foreperson who will be responsible for communicating with the court as needed.

You should then begin your deliberations. Your verdict on each issue must be unanimous. There will be a Verdict Form in the jury room waiting for you when you retire for your deliberations.

You will note that the Verdict Form has a series of questions to be answered during the course of your deliberations that corresponds to the jury instructions I've just given you. When you reach a unanimous verdict as to each question on the Verdict

Form, the foreperson is to fill in the answers on the Verdict Form.

Please make sure to read the questions carefully; and note that some of the questions may not require answers, depending how you answer other questions.

Do not reveal your answers to any of the questions to anyone outside of the jury until you return your verdict and are discharged. Also, if there is a divided vote on any of the issues at some point during your deliberations, you should not reveal how the vote is divided on any issue, even to me.

It frequently happens that there is disagreement among jurors when they begin deliberating, but part of your responsibility as jurors is to continue to deliberate in order to attempt to reach a unanimous verdict on each of the questions you are being asked to answer. In the course of respectful discussion among the jurors, it is almost always the case that the jurors can reach a unanimous verdict even if they are divided at the outset.

When you return to the courtroom to announce your verdict, please bring the completed Verdict Form with you.

Now, during your deliberations you must not

communicate with or provide any information to anyone other than your fellow jurors about this case. This includes through the use of any electronic device or media such as a smartphone or a computer or by way of the Internet or any Internet service or text or instant messaging service, any Internet chat room, blog, or website such as Facebook, LinkedIn, YouTube, or Twitter.

In short, you may not provide information to anyone about the case or conduct any research about the matter until I accept your verdict. I should add that the court security officer, Mr. Johnson, as well as other persons, is forbidden to communicate in any way or manner with any member of the jury on any subject touching the merits of the case.

Of course, you can have contact with Mr. Johnson and Ms. Martin, the chief deputy clerk, or other court staff as necessary to deal with any needs you may have; but you should not speak with them or anyone else about the case itself. This is your business as long as you are deliberating.

Now, it is important to add the caution that nothing said in these instructions and nothing in any Verdict Form prepared for you is meant to suggest what verdict you should return. What the verdict shall be is your sole and exclusive duty and responsibility.

Now, I expect when you get to the jury room to begin your deliberations, you may feel a little overwhelmed. This has been a very complicated case, and there is a lot of evidence and argument to think about. But I think you will be pleasantly surprised that as you start working methodically through the case, things will begin to seem more manageable.

I hope and expect that you will listen to one another's views respectfully, even if initially you disagree on some issues. Discussing the issues from different perspectives can often help in formulating your own ideas about how particular issues should be decided.

If you wish to see any of the exhibits, you are free to see them. All you need to do is have your foreperson sign a note asking for the exhibit and to provide that note to Mr. Johnson or any other court security officer who might be taking care of you at the time. You can ask to see all the exhibits, or you can just ask to see some of them. It's your choice. Just let us know what you want, and we will get those exhibits for you.

If you have a question or otherwise want to communicate with me at any time, please follow the same procedure by providing a written message or question to the court security officer, who will then bring it to me.

You probably will not get a reply right away because I usually need to summon all the lawyers and get their input before I can respond to the questions. That just means that I usually can't get back to you right away, but we will do our best to get you an answer to your question as soon as we can.

If you do have a question that is hanging you up, you are entitled to ask. I will tell you, however, that once the case is submitted to you, as it will be in a moment, we will not be able to take any additional evidence; and I may just have to tell you to rely on your collective recollection of what the evidence was and tell you that you have to decide the case based on the evidence you have heard.

I think you will find that in most instances, if you put your heads together, you will recall the evidence that you need to get over the problem. That's one of the reasons there are eight of you. Eight memories are better than one.

Finally, and most importantly, trust your common sense throughout. As I mentioned earlier, the founding fathers of this country had great confidence in the sound, common sense of an American jury. They had confidence in you to do your job diligently and well. The parties in this case have confidence in you, and so

do I.

Thank you. You may now retire for your deliberations.

(The jury exits the courtroom, 11:13 a.m.)

(Open court, all parties present, jury not present.)

THE COURT: Okay. Please be seated.

Do we have any further matters that we need to take up.

MR. VITAL: No, your Honor.

MR. BARRON: No, your Honor.

THE COURT: All right. I have two matters that I would like to put on the record before we adjourn.

The first has to do with something that I neglected to say at the time of the Rule 50(a) ruling on willfulness. And I alluded to this point earlier, but I will now make clear for the record that on willfulness, had willfulness gone to the jury and had there been a verdict of willful infringement in this case, I -- based on the evidence I heard in the course of the trial, I would have exercised my discretion not to award enhanced damages under 35 USC, Section 284.

The second point I'd like to make is a point -- well, Ms. Veazey has just left, but I wanted to extend my appreciation to Ms. Veazey, the courtroom

deputy; to Ms. Bickham, the very hard-working court reporter -- I'm afraid I've been a very tough task master -- here is Ms. Veazey.

I was just expressing my appreciation to your work and that of Ms. Bickham during the trial and also to Mr. Johnson and to Ms. Martin and the entire court staff. This courtroom -- the courthouse, as I've said on numerous occasions, is a remarkably efficient and cordial place. It is as friendly as it is efficient. They really know how to handle juries and to make things as comfortable as possible for the parties, and, I have to add, for visiting judges; and I admire them enormously for that.

Right now they have three trials going at once, which turns out is not actually a record, but it's remarkable that with as small a staff as they have they are able to do this seamlessly. So I appreciate that.

And one other group of people I'd like to thank is a group of people that we don't see, which is you're all getting daily transcript, I assume. Yes. And that means that unbeknownst -- well, perhaps beknownst, but unseen, are the people that are working late into the night to produce these transcripts, and I just think they need some acknowledgment as well because that is hard, hard work and I appreciate it.

And, finally, I appreciate the professional presentations made on the part of the parties in this case and the lawyers. It has been a pleasure to preside over the trial.

So, let's adjourn. If we get notes or other communications from the jury, we will contact you. And have, I hope, a more relaxed lunch.

Thank you.

(Recess, 11:17 a.m. to 12:58 p.m.)

(Open court, all parties present, jury not present.)

THE COURT: Okay. We have a note which I will share with you, and I have some thoughts.

Okay. Well, we have actually two notes; but only one of them is really pertinent. The first note reads, "We, the jury, nominate Dick Tracy, Jr., as our foreman."

The second note, which is pertinent, reads as follows -- and it's from "D.T.," Mr. Tracy, I assume -- "How long do we have to get to an animous" -- clearly meaning unanimous -- "vote?"

So, I'm open to suggestions. I have one which I will throw out, but this may be an occasion in which we might want to get ahead of the curve a little bit by having someone do a little research on the state of the

Allen charge in Fifth Circuit law which --

MR. HUGHES: It's only 1:00.

MR. VITAL: Right.

THE COURT: I know. It's only 1:00

Here is my take on this. It could mean one of two things. It could either mean how long do we have to stay here, or it could mean is there a limit on the amount of time within which we have to decide -- to get to the verdict.

I would think at this point the best thing to do would be to construe the note in the first -- excuse me -- the second thing; that is to say that they are asking whether they need to decide within a fixed period of time, the answer to which is simple. No.

MR. VITAL: Right.

THE COURT: And then to add something to the effect of keep going until you get there, without putting any kind of suggestion that, you know, we'll keep you the whole weekend if we have to.

As far as -- I think it would be premature to give any kind of *Allen* charge at this point. I mean, they haven't indicated deadlock; although, there may be some hints of that at least. But the problem with the *Allen* charge is, as you-all have dealt with this before -- is that once you use it, you've used up your

bullet. And I would be inclined to do something more modest at first; and then if they come back and they still have problems, then we can push them a little harder.

There is a lot of sensitivity about the *Allen* charge; and I would think it would be wise for us to have a good handle, which I haven't looked at Fifth Circuit law on *Allen* charges for probably -- well, for 24 years.

MR. VITAL: Your Honor, there is a pattern instruction.

THE COURT: Is there? Okay. Well, I'll --

MR. VITAL: There is a pattern for civil cases.

THE COURT: Yeah. I assume there is; so, I don't think we have to do any real deep research. But this is one of those occasions in which pattern instructions would seem to have a real appeal because we know that it has been blessed by the Fifth Circuit, and that's good.

MR. VITAL: Right.

THE COURT: So, here is my proposal -- and I'm all ears for any others -- something like this: There is no specific time limit within which you are required to reach a unanimous verdict. For now, you should continue to deliberate in an effort to reach a verdict on which

you can all agree.

Does that language -- one concern -- and I suppose this may be not terribly likely, given the fact that "unanimous" was not, you know, spelled -- it's spelled A-N-I-M-O-U-S, and that could just be a glitch. But I want to make sure that they understand the concept that you all have to agree; so, I'm putting that in the second sentence.

Everybody okay with this?

MS. SMITH: Yes.

MR. VITAL: Yes.

THE COURT: Okay. Why don't we get the jury, and I will so instruct them.

MR. MORTARA: Your Honor, should we close the doors to the courtroom; or do you want to leave them open?

THE COURT: Leave them open. I mean, it is an open court.

MR. MORTARA: They are usually shut when we have court. That's why I asked.

THE COURT: Oh, no. There's no reason. It's a little warm in here. I don't think there is any reason. We have open court.

Actually, Jill, could I have the note just so that -- I will read it to them to make sure that we are

all -- that this is consistent with their concerns.

(The jury enters the courtroom, 1:03 p.m.)

THE COURT: Ladies and gentlemen of the jury, we have a note from you and we've conferred and we have an answer which may help.

What the note says is, "How long do we have to get to a unanimous vote?" And our answer is that there is no specific time limit within which you are required to reach a unanimous verdict. For now, you should continue to deliberate in an effort to reach a verdict on which you can all agree.

I hope that's helpful. And you should now retire and continue to deliberate, if you would. Thank you.

(The jury exits the courtroom, 1:05 p.m.)

THE COURT: Okay. And if anyone has any comments, suggestions, or any other observations, I'm all ears.

MR. VITAL: We don't have anything, your Honor.

THE COURT: Okay. Any comments?

MS. SMITH: No, your Honor.

THE COURT: All right. Why don't we do this. Let's -- I don't think this is going to be difficult. As Mr. Vital points out, there are standard

circuit-blessed -- and the fact that it is Fifth Circuit-blessed, this is going to be Fifth Circuit law for sure, even though it will be in the Federal Circuit potentially -- but a Fifth Circuit-blessed *Allen* charge just in case we need so we don't end up scrambling if we find ourselves at 3:00 or 4:00 with a jury coming back reporting deadlock. You can divide the labor however you want to.

Thank you.

Actually, you know, it occurs to me -- I say "*Allen* charge" because I -- you know, when I used to do this, it was all criminal; and that was -- the *Allen* case is a criminal case. Do they --

MR. MORTARA: It is still *Allen*. We just had a two-*Allen*-charge trial. Yes, it is still *Allen* in a civil case.

THE COURT: All right. Well, I don't know if Fifth Circuit does this; but I know some circuits divide the *Allen* charge into stages to try to avoid, you know, too much intimidation at the first stage but to kind of push a little harder at the later stages. But that will be in the standard form, I expect.

MR. VITAL: Yes, it will.

THE COURT: Good.

MR. MORTARA: Thank you, your Honor.

THE COURT: Thank you.

(Recess, 1:07 p.m. to 4:08 p.m.)

(Open court, all parties present, jury not present.)

THE COURT: We have a note. I think the answer is going to be easy, but you may think otherwise. And I'll read it to you. It starts: Final Jury Instructions. In the middle of page 15, does the sentence mean, quote, person of ordinary, quote, mean in the art, which is underlined, as shown on example -- and then the sentence isn't finished.

But I think the gist of it is that the question is does "person of ordinary skill" mean "person of ordinary skill in the art," the answer to which seemingly is a resounding yes.

Now, there are a couple of ways we could do this. We could haul them in here and tell them, "The answer to your question is 'yes'"; or we could send them a note back, which I would be perfectly content to do, and avoid making quite as much of a big show.

MR. HUGHES: We would prefer to call them back.

THE COURT: Do you?

MR. HUGHES: Yes, please.

THE COURT: Okay. That's fine. We'll do

that.

Does anybody have anything other than the word "yes" to suggest?

MR. VARE: No.

MR. VITAL: Not from us, your Honor.

MR. HUGHES: No, sir.

THE COURT: Okay. Why don't we call them back.

(The jury enters the courtroom, 4:14 p.m.)

THE COURT: Ladies and gentlemen of the jury, you've asked a question about wording on the middle of page 15, specifically does the sentence that refers to a person of ordinary skill mean in the art.

And the answer to that question is yes, it does. I hope that's helpful to you.

Okay. Very well. Thank you.

(The jury exits the courtroom, 4:15 p.m.)

THE COURT: Okay.

MR. VITAL: Were you all able to find the civil --

THE COURT: Yes. We were able to find the pattern charge. I think it's a 2014 version, which I suspect -- since this goes back many years, I suspect it's the same even if there is a later version. But we also were able to find some case law that sort of fills

in with respect to such factors as how long, what kind of predicate there has to be for -- such as some kind of announcement of deadlock. There are a variety of factors, but I think we have a pretty good handle on what's necessary --

MR. VITAL: Thank you, your Honor.

THE COURT: -- to trigger the *Allen* charge.

Nonetheless, I think -- well, let me suggest that it might be a good idea for you-all if you can briefly confer. And if you agree on particular language, if we get to the point of the *Allen* charge -- presumably the language of the pattern charge. But if you have any departures that you want to suggest from that, if you first would meet and confer on that, it will save us potentially some time.

MR. VITAL: I will do that.

THE COURT: So, it would be nice if we could come in here with a -- I've actually written out both the pattern charge and multiple copies for the jurors in case having it in writing would be helpful to them.

MR. VITAL: Yes, your Honor.

THE COURT: If you don't agree with the pattern charge, it would be helpful to know.

MR. VITAL: Yes, your Honor.

THE COURT: Good. Thank you.

(Recess, 4:17 p.m. to 5:38 p.m.)

(Open court, all parties present, jury not present.)

THE COURT: Okay. We have a verdict. So, if everybody is settled in.

Mr. Johnson, could you bring in the jury, please.

(The jury enters the courtroom, 5:39 p.m.)

THE COURT: Mr. Tracy, as foreman of the jury, do you have a Verdict Form?

THE FOREPERSON: Yes, we do, your Honor.

THE COURT: Could you give that to Mr. Johnson, please.

Thank you.

I will now read the verdict question by question.

Question Number 1. Has UroPep proved by a preponderance of the evidence that Lilly induced infringement of claim 1 of the '124 patent? (For the judge's instructions on infringement, see Instruction Numbers 1 through 3 in Part III of the instructions.)

Answer, yes.

Question Number 2. Has Lilly proved, by clear and convincing evidence, that claim 1 of the '124 patent is invalid for any of the following reasons?

A, anticipation. No.

B, obviousness. No.

C, lack of written description. No.

D, lack of enablement. No.

Question Number 3. What is the reasonable royalty that UroPep is entitled to receive from Lilly for infringing the '124 patent?

$20 million.

It is dated 4-21-17. Dick Tracy, Jr., jury foreman.

Now, does anybody want me to poll the jury?

MR. VITAL: For Lilly, only at your pleasure, your Honor. We are fine with however you choose to proceed. I understand --

THE COURT: If you don't want to poll the jury, I think it makes --

MR. VITAL: We don't have a --

THE COURT: That's fine.

MR. VITAL: -- specific request but --

THE COURT: That's fine.

MR. VITAL: -- your Honor could do it.

THE COURT: We'll just -- let me give Ms. Veazey the Verdict Form.

All right. I just want to express our sincere thanks for the hard work you've done this week, and I

know this is a very difficult case and you've worked very hard. You've been very attentive. And on behalf of the court staff and this whole Eastern District court, we are very grateful for your service.

Now, I would like you now to go with Mr. Johnson back to the jury room, if you would, and wait for me. I'll be in there in just a moment, and I want to have an opportunity to discharge you and greet you individually and personally.

As to going forward, you are free to talk about this case to anyone that you want; but you are also free not to talk about it if you don't want to. So, the lawyers will not approach you; but if you're interested in talking to the lawyers, they will be happy to do that.

So, you are done with your service as soon as I discharge you in just a couple of moments. But once again thank you so much.

Court is adjourned.

(The jury exits the courtroom, 5:42 p.m.)

THE COURT: Actually, I said court is adjourned; but is there anything that anyone needs to further -- any other matter anyone needs to raise?

MR. VITAL: I'm just happy to go home and sleep in my own bed tonight.

THE COURT: Nothing other? Now the court is adjourned. Thank you.

(Proceedings concluded, 5:43 p.m.)

COURT REPORTER'S CERTIFICATION

I HEREBY CERTIFY THAT ON THIS DATE, APRIL 21, 2017, THE FOREGOING IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS.

/s/
CHRISTINA L. BICKHAM, RMR, CRR